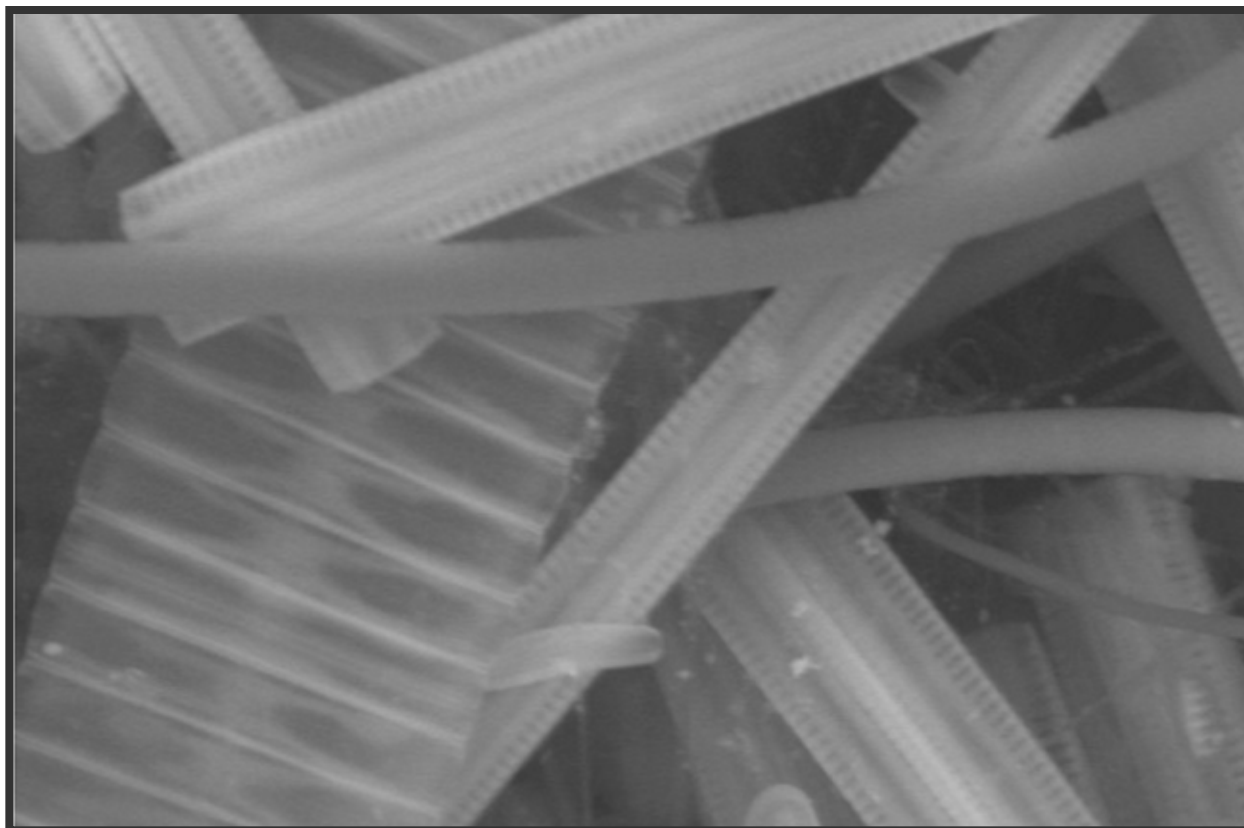




Thesaurus Of Terms Used In Microbiological Risk Assessment



This document is available on EPA's web site at
<http://www.epa.gov/waterscience/criteria/humanhealth/microbial/>

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ACKNOWLEDGMENTS

Project Leader

Stephen Schaub Principal Author and Contact
U.S. EPA Office of Science and Technology

Technical Reviewers

Gary Bangs	U.S. EPA, Risk Assessment Forum
Jamie Bartram	World Health Organization, Water, Sanitation, and Health Programme
Brendlyn Faison	U.S. EPA, OW/OST
Barbara Klieforth	U.S. EPA Office of the Science Advisor, Science Policy Council
Alecia Naugle	U.S. Department of Agriculture, Food Safety Inspection Service
Tonya Nichols	U.S. EPA National Homeland Security Research Center, Threat and Consequence Assessment Division
Carl Schroeder	U.S. Department of Agriculture, Food Safety Inspection Service
Mark Segal	U.S. EPA, OPPTS
Brandolyn Thran	U.S. Army Center for Health Promotion and Preventive Medicine
Philip Berger	U.S. EPA, OW/OGWDW
William Schneider	U.S. EPA, OPPTS
John Ravenscroft	U.S. EPA, OW/OST
Laura Philips	U.S. EPA, OW/OWM
Bridgid Curry	U.S. EPA, OPEI
Leslie Darman	U.S. EPA, OGC

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CHAPTER ONE: INTRODUCTION

The United States Environmental Protection Agency's (EPA) Office of Water has developed this Thesaurus of Microbiological Risk Assessment (MRA) Terms because it is important for risk assessors, managers, and communicators to have available and to use common, understandable terms and definitions for the various facets of the MRA process. This Thesaurus is a collection of definitions of terms that may be relevant for microbial risk assessment (MRA). It should help risk assessors, managers, and communicators become aware of various definitions so that they can better communicate with each other and avoid misunderstandings. It should also help increase transparency and contribute to a common understanding of the MRA process and presentation of MRA results.

Currently, various program offices within EPA, as well as other Federal Agencies (e.g., Food and Drug Administration [FDA] and United States Department of Agriculture [USDA]) and International Agencies (e.g., World Health Organization [WHO] and Food and Agricultural Organization [FAO]), utilize terms often unique to the activities or MRA applications for that specific agency. Different Agencies may also have different operating definitions for the same term. This Thesaurus seeks to identify the terms that have the most potential to cause confusion due to varying uses for terms.

1.1 Background and Scope

Risk assessment is an important tool used by a variety of disciplines or fields of study. Because the different fields of risk assessment use their own methods and terms and also borrow from other scientific disciplines, much of the nomenclature is broadly used, but narrowly defined within a field. In addition, similar concepts may go by different names in different fields. For example, in ecological risk assessment a stressor interacts with a receptor, whereas in chemical risk assessment for human health scenarios, toxicants (or toxins) interact with humans through various exposure routes. In MRA, hazards interact with hosts either through "primary" and "secondary" exposures. Pointing out these differences is not meant to suggest that these differences are inappropriate, but to help designers and users of risk assessment understand that these differences exist so that as the science of risk assessment evolves, it is less likely that any given term is adopted for multiple uses.

The major fields of risk assessment that contributed terms and definitions to this Thesaurus include:

- air toxics risk assessment (risks to humans from inhaled toxins)
- carcinogen risk assessment (risks to humans from mainly chemical carcinogens)
- ecological risk assessment (risks to wildlife and ecosystems)
- environmental risk assessment (risks to the environment)
- food safety risk assessment (risks to humans from consumption of food)
- microbial risk assessment (risks to humans from microbial pathogens)
- nuclear radiation risk assessment (risks to humans from radiation exposure)
- water safety risk assessment (risks to humans from drinking water, recreation, or other water)

uses)

Because risk assessment is multi-disciplinary, terms and definitions from contributing disciplines are often adopted. Term preference is often determined by the risk assessor's educational background and areas of expertise. Disciplines that contribute to risk assessment terminology include, but are not limited to: biology, chemistry, computer science, economics, epidemiology, law, mathematics/statistics, medicine (clinical), microbiology, pharmacology, philosophy, policy, toxicology and veterinary sciences. In addition, terms may be favored or disfavored by different government agencies. In many cases the terminology adopted by an agency comes from the legislations that enable that agency's regulatory authorities. Risk assessors, managers, or communicators that are isolated in one agency's working culture may not be familiar with how risk assessment terms are used in other agencies.

Terms are generally proposed and modified by mostly informal processes that involve communication between policy makers, risk assessors, industry, academia, the general public, and other stakeholders. One example of the process of creating a definition is when the definition of a term is presented in a draft guidance document and then commented on by stakeholders. In some cases, terms are included in statutes, so they have legal definitions within that context. One example is "safety factor" that is defined by statute for food additives, but has non-legal definitions in other contexts. More formal efforts for evaluating definitions are carried out by the Organisation for Economic Co-operation and Development (OECD) and the International Programme of Chemical Safety (IPCS), such as their joint project on the Harmonisation of Hazard/Risk Assessment Terminology (IPCS/OECD 2004) and the work of the IPCS Exposure Terminology Subcommittee (IPCS 2001).

This Thesaurus of terms and definitions has been compiled based upon existing risk assessment related documents prepared by various national and international entities having responsibilities for conducting, interpreting, or using risk assessments (especially related to microbiological risks). It is not intended to provide all terms and definitions that may be used for various science applications in all facets of microbiology, ecology, chemistry, biology, etc. The intent of this document is to capture those terms and definitions which appear to have significant risk assessment applications as identified in existing documents. It should be noted that there also may be a few gaps in risk assessment related terms or definitions that were not provided by the various documents searched in the present effort.

This Thesaurus contains a few terms or definitions which are used in specific regulations; however, the bulk of relevant regulatory terms are not included because they have specific definitions that are context-dependent. Any terms identified here as regulatory definitions should not be considered as the definitive source and should be further examined in the referenced regulatory document. It is important for anyone using this Thesaurus to know that in certain regulatory uses of terms there may be a specific context for the definition and additional background information for its uses may be provided in that regulatory document that are not covered here. Because there is an authoritative source for the definitions of regulatory and statutory terms (they can be found in the Code of Federal Regulations or the United States Code) they are not covered comprehensively in this Thesaurus.

1.2 Sources Consulted

Numerous (mostly online) glossaries, lists of terms and definitions, and publications were consulted during the development of the Thesaurus. Throughout the Thesaurus, primary (and in some cases secondary) sources for each definition are indicated. The primary sources consulted are briefly described below. Complete references for all primary sources, including URLs (as available), are provided in the Reference section at the end of the Thesaurus.

EPA Sources:

- The EPA-International Life Sciences Institute (ILSI) *Revised Framework for Microbial Risk Assessment* (ILSI 2000) has been EPA Office of Water's working MRA framework. For this thesaurus, the EPA-ILSI 2000 framework glossary as well as several terms included in the text, but not listed in the glossary, provided the basic list of terms. This is the only document for which definitions are taken from the main text as well as from the glossary.
- EPA's Integrated Risk Information System (IRIS) has an online glossary of terms (EPA 2003). IRIS is an electronic database containing information on human health effects that may result from exposure to various chemicals in the environment. IRIS was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making, and regulatory activities.
- EPA is currently developing an air toxics risk assessment (ATRA) reference library for conducting air toxics analyses on facility and community scales. This effort will result in a three-volume library that provides information on the fundamental principles of risk-based assessment for air toxics and how to apply those principles in different settings, as well as strategies for reducing risk at the local level. Volume 1 (EPA 2004) discusses the overall air toxics risk assessment process and the basic technical tools needed to perform these analyses. The manual, which covers both human health and ecological analysis, also provides a basic overview of risk management and communication. Other tools (such as the public health assessment process) are described to give assessors, risk managers, and other stakeholders a more holistic understanding of the many issues that may come into play during air toxics risk assessment and reduction projects. An extensive glossary, which compiles definitions from many EPA sources is included. The disclaimer notes that definitions used therein are not official EPA definitions.
- The EPA *Exposure Factors Handbook* (EPA1997a) provides summary statistical data on exposure factors necessary to assess human exposures to environmental contaminants. The glossary has terms that are related to exposure.
- EPA's Office of Wetlands, Oceans and Watersheds published *Ecological Restoration: A Tool to Manage Stream Quality* (EPA 1995a) with four objectives related to the Clean Water Act and stream restoration. Chapter 8 of this seminal report includes a glossary of ecological restoration-related terms that are relevant to this Thesaurus and which was last updated on August 18, 2003.
- The EPA *Guidelines for Ecological Risk Assessment* (EPA 1998a) includes a glossary of terms. The EPA/ILSI 2000 framework is based on the basic risk assessment structure that is presented in that report.
- EPA published *Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for*

Assessing Susceptibility from Early-Life Exposure to Carcinogens in March of 2005 (EPA 2005a). There are a few footnotes that provide definitions relevant to MRA.

- The EPA Office of Communications, Education, and Public Affairs (OCEPA) maintains an online glossary called *Terms of Environment*, which defines in non-technical language the more commonly used environmental terms appearing in EPA publications, news releases, and other Agency documents available to the general public. The definitions do not constitute the Agency's official use of terms and phrases for regulatory purposes. Although the printed version of the glossary was last revised in 1997, the website version from June 13, 2005 was used for this Thesaurus (EPA 2005b).
- The National Health Environmental Effects Research Laboratory of EPA's Office of Research and Development maintains an online *Definitions of Terms* within the Aquatic Resources Monitoring Web Site, which contains terms and definitions relevant to this Thesaurus and was last updated on July 7, 2005 (EPA 2005c).
- EPA's Technology Transfer Network Air Toxics Website includes an online *Glossary of Health, Exposure, and Risk Assessment Terms and Definitions of Acronyms* that is relevant to this Thesaurus and was last updated in February 2005 (EPA 2005d).
- EPA's online *Pesticides Glossary* was consulted for terms that are relevant to MRA. (EPA 2005e)
- EPA Office of Water's Draft *Methodology for Deriving Microbial Ambient Water Quality Criteria for the Protection of Human Health* was also used as a source for a few definitions. (EPA 2005f)

Other U.S. Sources:

- The U.S. Centers for Disease Control and Prevention (CDC) provide and maintain an online *Reproductive Health: Glossary* that includes several medical, epidemiological, and risk assessment terms and definitions that are included in this Thesaurus. The CDC glossary was last updated on April 6, 2005 (CDC 2005).
- The FDA, Center for Food Safety and Applied Nutrition (CFSAN) has published *Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework: A Report by the CFSAN Risk Analysis Working Group* (FDA 2002). The glossary of terms closely agrees with the international definitions put forward by the Codex Alimentarius Commission.
- The FDA CFSAN provides the A to Z Comprehensive List of Terms (FDA 2001) as part of the online "Food Safety A to Z Reference Guide." This list contains several terms and definitions that are relevant to this Thesaurus.
- The Agency for Toxic Substances and Disease Registry (ATSDR) is an agency in the Department of Health and Human Services. ATSDR was created by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, also known as Superfund) and is responsible for assessing health issues and supporting public health activities related to hazardous waste sites or other environmental releases of hazardous substances. An online glossary defines words used by ATSDR in communications with the public (ATSDR 2004).
- Risk Assessment Information System (RAIS) is an internet-based resource for risk assessment tools and guidance. It is supported by the U.S. Department of Energy (DOE), Office of Environmental Management, and Oak Ridge Operations (ORO) Office through a

contract with Bechtel Jacobs Company LLC. The Glossary of Useful Terms Found in Risk Assessment cites other sources that were used in this Thesaurus; therefore most of the RAIS terms are duplicative (RAIS 2004).

- The U.S. Navy Environmental Health Center's Environmental Programs Directorate has been the Navy's risk communication expert since its inception in 1991. Their website, Risk Communication: Navy Health Operational and Environmental Issues, includes an online Glossary (Navy 2002) that includes a few terms and concise definitions related to risk communication that are included in this Thesaurus.
- The website Navy Guidance for Conducting Ecological Risk Assessments includes an online Glossary (Navy 2003) that includes a few terms and definitions that are relevant to this Thesaurus.
- The website for the Travis Air Force Base Environmental Restoration Program includes an online Glossary (TAFBERP 2005) from which one term and definition are included in this Thesaurus.
- The U.S. Department of Transportation report *Probabilistic Risk Analysis for Turnkey Construction: A Case Study; Final Report* (USDOT 1996) includes a Glossary from which one term and definition are included in this Thesaurus.
- The U.S. Nuclear Regulatory Commission provides and maintains an online Basic References: Glossary (USNRC 2005) from which one term and definition are included in this Thesaurus.
- The U.S. National Institute of Standards and Technology provides and regularly maintains an online *Dictionary of Algorithms and Data Structures* (NIST 2005) that includes several terms and definitions related to statistical processes and modeling that are included in this Thesaurus.
- The *e-Handbook of Statistical Methods* (NIST/SEMATECH 2005a) is an Internet-based book whose goal is to help scientists and engineers incorporate statistical methods into their work as efficiently as possible. It is intended to serve as a useful educational tool that will help users of statistical methods and consumers of statistical information better understand statistical procedures and their underlying assumptions and more clearly interpret scientific and engineering results stated in statistical terms. Several statistical terms and their definitions from this online book are included in their entirety or in abbreviated form in this Thesaurus. The book also includes a semi-independent online Glossary (NIST/SEMATECH 2005a), which contains several terms and definitions that are also included in this Thesaurus.
- Managing Effective Risk Response: An Ecological Approach (MERREA) seeks to improve risk management by helping individuals and agencies to predict, inform, and manage the responses of the various stakeholders involved in any risk event more openly and effectively. Their website provides and maintains an extensive Glossary of Risk Management (MERREA 2005) which includes several terms and definitions that are included in this Thesaurus.
- The National Library of Medicine's National Information Center on Health Services Research and Health Care Technology provides an online glossary (NLM/NICHSR 2004) of clinical and statistical terms that are relevant to this Thesaurus.
- The New York State Governor's Office of Regulatory Reform's *Cost-Benefit Handbook: A Guide for New York State's Regulatory Agencies* (NYS 1998) includes a glossary of economic and risk assessment terms in Appendix A. Several of these terms and definitions

are included in this Thesaurus.

- The USDA Economic Research Service (ERS), maintains A Safe Food Supply Glossary on their website (USDA 2004). Terms from this glossary highlight how risk assessment can include economic factors.
- The Rehabilitation Research and Training Center on Positive Behavior Support of the University of South Florida includes an online Glossary (RRTC-PBS 2003), which includes a few terms and definitions that are included in this Thesaurus.
- Research Professor E. Bruce Brooks (Brooks 2001) of University of Massachusetts, Amherst, has provided an online glossary for Acquiring Statistics: Techniques and Concepts for Historians since 2001 that provides concise definitions for several statistical terms that are relevant to this Thesaurus.
- The Society for Risk Analysis Committee for Definitions maintains an online Glossary of Risk Analysis Terms (SRA 2004) which has not been officially adopted or endorsed by SRA but is relevant to this Thesaurus.
- MathWorld is a comprehensive and interactive mathematics encyclopedia intended for students, educators, math enthusiasts, and researchers and is continuously updated to include new material and incorporate new discoveries. Several mathematical and statistical terms and definitions from this website (Weisstein/MathWorld 2002, 2003, 2005a, b) are included in this Thesaurus.

International Sources:

- Codex Alimentarius Commission was created by the FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. Since its formation in 1963, Codex has been an internationally acknowledged source for terms and definitions used throughout food related policies. Water and food are related because both are intentionally consumed and can harbor pathogenic microorganisms, therefore MRA frameworks and tools developed for use in food media are very often applicable for water media. Included in this Thesaurus are terms from three Codex publications—the twelfth and thirteenth editions of the procedural manual, and *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC 1999, 2002, 2003)
- ILSI Europe has published a *Concise Monograph Series, Principles of Risk Assessment of Food and Drinking Water Related to Human Health* (ILSI 2001). This document is distinctly different from the EPA-ILSI framework mentioned above. The European publication follows the chemical risk assessment paradigm, whereas, the EPA-ILSI (2000) framework follows an environmental paradigm. Terms are from the glossary that is included in the monograph.
- The Organisation for Economic Co-operation and Development (OECD), in a joint project with the International Programme of Chemical Safety (IPCS) on the Harmonisation of Hazard/Risk Assessment Terminology, has published a *Description of Key Generic Terms Used in Chemical Hazard/Risk Assessment* (IPCS/OECD 2004). The report includes a survey of 186 risk professionals from around the world and their ranking of various definitions for terms. The final output of this effort will be an annotated glossary of terms reflecting the situation that emerges from the responses to the survey. The comments that committee members submitted for different terms are included in the report and serve as a

list of observations about the definitions. Some of the terms evaluated during the OECD project are included in this thesaurus.

- The Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) have published *Hazard Characterization for Pathogens in Food and Water Guidelines* in their Microbiological Risk Assessment Series (FAO/WHO 2003a), which includes several definitions that are relevant to this Thesaurus.
- The FAO and WHO published *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* to enable national authorities, particularly in developing countries, to improve their food control systems (FAO/WHO 2003b). Annex 1 of the report includes a Glossary with several terms and definitions that are relevant to MRA and this Thesaurus.
- The online World Bank, Human Capital Development and Operations Policy Working Paper The Disability-Adjusted Life Year (DALY) Definition, Measurement and Potential Use (World Bank 2004), was cited directly to provide a definition for this important term.
- The framework document, *The Interaction Between Quantitative Microbial Risk Assessment and Risk Management in the Water Safety Plan* (KIWA 2004), was prepared by Kiwa Water Research and the University of Delft (both of The Netherlands) in collaboration with the Institute of Infectious Disease Control (Sweden), Anjou Recherche (France), Veolia Water Partnership (UK), WRc-NSF (UK), Bonn University (Germany), Ondeo Services (France), University of East Anglia (UK), University of New South Wales (Australia), and Water Technology Centre (Germany). The framework is part of a larger research project called “MicroRisk: Scientific Basis for Managing Drinking Water Safety from Source to Tap,” that is co-financed by the European Commission (Contract EVK1-CT-2002-00123). Many terms from the framework glossary are included in this Thesaurus.
- The Food Standards Agency (FSA) of the UK was created by an Act of Parliament in 2000 to be an independent food safety entity to protect public health and consumer interests in relation to food. Some definitions relevant for risk assessment from the FSA online glossary are included in this Thesaurus (FSA 2005).
- The Australian Academy of Science (AAS) provides online versions of their periodic *Nova* reports that focus on the science behind a variety of technology and policy topics. One such report, entitled *Good Prospects Ahead for Data Mining*, includes a glossary of decision-making and networking terms and definitions that are relevant to this Thesaurus.
- The Cooperative Research Centre for Water Quality and Treatment (CRCWQT) provides a national strategic research capacity for the Australian water industry. It also provides an online Glossary of Water-Related Terms (CRCWQT 2002) that includes several terms and definitions that are included in this Thesaurus.
- The New Zealand Ministry for the Environment publication, *Freshwater Microbiology Research Programme Report: Pathogen Occurrence and Human Health Risk Assessment Analysis*, includes a glossary of terms (NZ 2002). Definitions for terms relevant to risk assessment are included in this Thesaurus.
- Canada’s *General Risk Assessment Framework for the Ontario Ministry of Agriculture and Food* (OMAF 1997) has core terms that generally agree with the Codex definitions for the same terms; however, the Canadian definitions are included due to their slight variation.
- The Department of Medical Oncology of the University of Newcastle upon Tyne (United Kingdom) provides and maintains an On-line Medical Dictionary as part of its CancerWeb

Project (CancerWEB 2005). Several definitions relevant for MRA from this online medical dictionary are included in this Thesaurus.

- The European Society for Opinion and Marketing Research (ESOMAR) provides an online Glossary of Marketing Research Terms (ESOMAR 2001) which includes several terms and definitions that are relevant to this Thesaurus.

CHAPTER TWO: ISSUES IN RISK ASSESSMENT TERMINOLOGY

Several issues regarding risk assessment terminology were identified during the development of this Thesaurus. Many terms have multiple definitions, some almost identical and some significantly different. Comparison of these definitions reveals that discrepancies between the meaning or usage of these terms often have historical roots, a result of the timing of or order in which risk assessment fields developed.

Several terms and roots of terms are used within the microbial risk assessment community in different contexts. This can potentially cause unnecessary confusion. A comprehensive harmonization of terms would be valuable to the microbial risk assessment (MRA) community. Similar activities are ongoing, such as the joint work of the International Programme on Chemical Safety (IPCS) and the Organisation for Economic Co-operation and Development (OECD) project on Harmonisation of Hazard/Risk Assessment Terminology (IPCS/OECD 2004), and the work of the IPCS Exposure Terminology Subcommittee (IPCS 2001). Terms from other risk assessment disciplines (environmental, epidemiological, chemical) should be adopted where appropriate and useful, although water and food are the major media for which MRA is currently being used. Harmonization between food and water MRA terms is also desirable.

Terms that often cause the most confusion are those that are used commonly in every language (in the vernacular), but within risk assessment have a more specific definition (e.g., transparency). In particular, multi-word terms may have highly developed definitions for risk assessment applications which are not necessarily implied by the assumed vernacular definition of each word in the term (e.g., data quality).

Terms that usually cause the least amount of confusion are those that are easily identified as technical or regulatory terms (e.g., benchmark dose) or are defined in a context-specific manner in published statutory or regulatory language (e.g., reference dose)—although the latter are generally not included in this Thesaurus, as discussed in Chapter 1.

There are some words that are used in combination with other words to create unique multiword terms. Some of the most obvious examples include: analysis, assessment, characterization, dose, effect, exposure, hazard, and risk. Examination of the definitions of the terms in this Thesaurus suggests that the most significant confusion occurs from overlap in terms used to describe the risk assessment process in various risk assessment frameworks.

Summary of Findings

Development of this thesaurus suggests:

- A harmonization of terms, especially between food and water terms, would be valuable to the microbial risk assessment community.
- The risk assessment community should use existing terminology rather than invent new

terms or new meanings for existing terms.

Factors that lead to confusion:

- Words used commonly in every language (in the vernacular) may have a specific definition within risk assessment.
- Multi-word terms may have definitions not obvious from the vernacular definition of the individual words.
- Overlap in terms used to describe the risk assessment process in various risk assessment frameworks.

CHAPTER THREE: DISCUSSION OF SELECTED TERMS

Specialized meanings, relative to both common and technical usages, can present a barrier to clear communication within a field. A number of terms from this Thesaurus have been identified as warranting an in-depth discussion of the potentially contradictory usages, based on their importance in risk assessment and the potential for causing confusion. The discussions below are in addition to the commentary on definitions found at the end of some entries.

3.1 General Terms

A few risk assessment terms merit discussion because they are fundamental to the nature of risk assessment and are frequently misunderstood. These such terms addressed below include: dose-response, endpoint, exposure, hazard/agent/stressor, uncertainty, and variability.

dose and dose-response

Dose is a general term that refers to total amount of a hazard/agent ingested or absorbed. This total amount depends on both the concentration in the media and the amount of the media.

The term dose implies that an exposure to some concentration has occurred. In this respect dose and exposure overlap somewhat in meaning and in some cases they are used synonymously, often erroneously so. Generally, exposure refers to individuals or populations while dose reflects the exposure level of individual (see, for example, “average dose”).

Dose covers a variety of more specific measurements, so it is often qualified with a term that limits its scope. For example, the amount of a hazardous agent that comes in contact with the external body may not be the amount that reaches the target organ (i.e., the dose or dosage). Terminology that recognizes the possibility that the concentration of the hazardous agent can change throughout the exposure scenario is useful for reducing confusion. Dose can have a temporal element as well. In a given case, dose can be defined by the duration of a continuous exposure or the pattern of repeated distinct exposures. Clear definition of what constitutes a dose for a risk assessment scenario can be difficult because a variety of exposure scenarios may be of interest.

The concept of dose bridges the gap between exposure and response. For a concentration to become a dose, exposure must occur. In addition, the response of concern is directly related to the dose. The dose-response relationship characterizes the relationship between the dose level and a probability of response. The response can be individual- or population-based. For example, exposure to a higher level of hazardous agent could result in more total illnesses in a population. Mathematical models are usually used to estimate dose-response relationships.

exposure

The term exposure is used in a number of different ways in risk assessment. It is generally understood to mean relevant contact between a person and a hazard. Factors that may affect an exposure include the concentration of the hazardous agent, the duration of contact, the target tissues or organs, and the route of exposure. Exposure can refer to populations or individuals.

exposure route versus exposure source

Exposure route (also known as “route of exposure”) most commonly refers to the manner in which a hazardous agent moves from the environment to target tissues or organs. Examples of exposure routes include inhalation (nose and mouth to lungs), ingestion (oral), dermal (skin), eyes, ears, and sexual. Which routes are relevant for a given hazardous agent depends on both the host (or receptor in ecological RA) and agent (pathogen in MRA; stressor in ecological RA) properties and is situation dependent. An exposure source can originate from either natural or anthropogenic events, activities, or locations that generate or release hazards. Exposure sources can be classified as point sources or non-point sources. An example of a point source is an industrial facility that releases untreated water into a river; an example of a non-point source is agricultural run-off. For MRA, a sewage treatment plant would be a commonly considered point source, whereas, urban run-off is a possible non-point source of pathogens.

An exposure pathway encompasses both exposure source and route, and generally is described by a source, an exposure point, and an exposure route.

endpoint

Endpoint is used differently in environmental versus human health risk assessment. In environmental risk assessment, endpoint refers to the environmental value that is being protected. Ecological attributes like biodiversity or a particular species like striped bass, are examples. In human health risk assessment, endpoint refers to a manifestation of adverse human health due to exposure to the hazard in question (also known as response in dose-response). Example MRA endpoints include infection, a defined set of symptoms, or death. Both environmental and human health assessments may address multiple endpoints. The significance of the endpoints are part of the justification for conducting the risk assessment. A poorly defined endpoint can lead to misunderstandings or inappropriate expectations from the risk assessment.

hazard/agent/stressor

Hazard, agent, and stressor can sometimes be used synonymously. However, there are cases where the terms need to be differentiated. For example, “stressor” is used in ecological risk assessment and includes the connotation that the adverse response can be the result of a lack of something – such as a habitat – which would be called a “stressor.” The term “agent” does not have this connotation. “Agent” is used to denote a causative entity that actually physically exists as part of the environment and can be used in either ecological or human health risk assessment. “Hazard” is used primarily in human health risk assessment, although “hazards” are not limited to “agents.” For example, the number of days spent in a hospital may be a hazard that correlates with risk of nosocomial infection.

uncertainty and variability

Uncertainty and variability are two frequently cited causes of uncertainty in the outputs of risk assessments or in the answers to questions posed by risk managers. It is sometimes important to be able to distinguish the causes of the uncertainty in order to better manage risks. Many different sources of definitions are available and several of them offer conflicting definitions of variability and uncertainty. In some of these variability is considered a source of uncertainty. An exception to this view is found in the EPA *Exposure Factors Handbook* (1997a), where the authors state:

While some authors have treated variability as a specific type or component of uncertainty, the U.S. EPA (in Guidance for Risk Characterization. Science Policy Council, 1995) has advised the risk assessor (and, by analogy, the exposure assessor) to distinguish between variability and uncertainty. Uncertainty represents a lack of knowledge about factors affecting exposure or risk, whereas variability arises from true heterogeneity across people, places or time. In other words, uncertainty can lead to inaccurate or biased estimates, whereas variability can affect the precision of the estimates and the degree to which they can be generalized.

Whether or not variability is considered a source of uncertainty, it is a theme in the definitions of both terms that variability should be distinguished from other sources of uncertainty. A practical reason for this is that other sources of uncertainty theoretically can be reduced through the collection of more data. Variability cannot be reduced by gathering more data, but can be reduced by narrowing the scope of the scenario that is being considered, or by dividing the variability into less variable subgroups and addressing the groups separately.

3.2 Framework Terms

Two of the most commonly used frameworks are the NRC model which has been adapted by Codex for MRA of food risks and the ecological model which has been adapted by ILSI and EPA for MRA of water related risks (CAC 1999; EPA 1998a; ILSI 2000; NRC 1983). The main terms that have different meanings between these two frameworks are analysis, characterization, and profile. How these differ is discussed below. Because these terms refer to different parts of risk assessment depending on the framework, there is potential for confusion. Therefore, clarification when using these terms should reduce confusion.

analysis

The EPA/ILSI MRA and EPA ecological frameworks use the term analysis differently than the NRC and Codex frameworks. Codex and NRC use “risk analysis” to refer to the whole field that encompasses risk assessment, risk management, and risk communication. The EPA/ILSI framework uses “analysis phase” to refer to the characterization of exposure and characterization of human health effects within a risk assessment. Therefore, there can be confusion if the term “analysis” is used without the appropriate qualifier, such as risk analysis or analysis phase.

characterization

The EPA/ILSI framework uses the term “characterization” in several places. The analysis phase consists of characterization of exposure and host characterization. The final phase is called risk characterization. Codex uses the term hazard characterization to refer to what the EPA/ILSI framework calls characterization of human health effects, which is also called dose-response in other frameworks (e.g., NRC 1983). Therefore the term characterization is commonly used in conjunction with other words as qualifiers. The term is used in its generic sense as well in specific context referring to a particular step in risk assessment. Confusion can be minimized if users are aware of the framework that is being used.

profile

This term is used in the EPA/ILSI MRA and EPA ecological frameworks to refer to the last part of the analysis phase of risk assessment. In the EPA/ILSI framework, a summary of the results of the infectious disease hazard (pathogen) characterization and the host characterization is conducted to arrive at an exposure profile and a host-pathogen profile. The international community (Codex) uses profile to refer to the initial stages of risk assessment where data is gathered and the risk assessment scope is defined. In contrast, the EPA/ILSI framework refers to this initial stage as problem formulation. Therefore the term profile is used to refer to two very different phases of microbiological risk assessment.

3.3 Infectious Hazard-Specific Terms

A microbial risk assessments (MRA) differs from other types of risk assessment in a variety of ways, and MRA terminology reflects this. The ability of microbes to multiply or die in the environment and the dynamic nature of host-pathogen interactions add a unique complexity to MRAs. The dynamic nature of the interaction of host, pathogen, and environment is commonly referred to as the “epi triad.” For describing fluctuations of microbes in the environment, terms used in chemical risk assessment can be applied without causing confusion. Terms like fate and transport, persistence, background level, and lower detection limit are often appropriately used and understood. The dynamic nature of host-pathogen interactions, unique to infectious disease risk assessment, has spawned some terminology that is frequently used but poorly articulated and defined. Two examples are provided below.

immune status

No general definition for “immune status” was found in the development of this Thesaurus. Immune status is a frequently used term, so it is surprising that definitions were not readily available. This may be because there are many ways to characterize the human immune system. “Immune status” refers to an individual’s (or population’s) degree of immune system functioning. Immune markers can include, but are not limited to, general indicators, such as T-cell count, and myriad specific markers, such as antibodies that confer acquired immunity. In addition, the general strength and specific abilities of an individual’s immune system fluctuates through time. It can refer to either individual or population based measures of immunity characteristics. The EPA/ILSI framework identifies the following factors as influencing immune status: age, genetic background, pregnancy, nutritional status, concurrent illness, and medical treatment (ILSI 2000). Because this is a very common term in MRA, therefore it would useful to develop a definition that is broad enough that all the current usages of the term are encompassed.

secondary spread/secondary attack rate/secondary transmission

Definitions for these analogous terms were not found in most of the sources consulted. In individual studies, secondary transmission can be defined for the study in question, but those definitions may not be consistent across studies. The most restrictive definition limits secondary transmission to cases arising from direct human-to-human contact between a primary case (infected or ill) and the secondary case who becomes infected or ill from that contact. Broader definitions include secondary cases that arise from contact with fomites or contaminated food or water. In the cases where secondary transmission includes infection from pathogens from the environment, the case would not

be considered secondary unless it occurs in the context of an outbreak where primary cases have already been identified. It may be difficult to distinguish between primary and secondary cases. For pathogens that infect only humans (no zoonosis or vectors) all infections ultimately arise from human to human contact or human to environment to human pathways. In these cases it is useful to limit the definition of secondary cases based on time and distance. For example, after a primary case is identified, only cases that occur within the time window of the primary case being infectious would be considered secondary transmission. For cases that occur during outbreaks a credible scenario for exposure between the primary and secondary cases would be important. Because there are many legitimate ways to define secondary transmission, it is important that the definition be elaborated for the situation being presented.

CHAPTER FOUR: HOW TO USE THIS THESAURUS

This Thesaurus is a selection of microbiological risk assessment related terms and definitions collected and compiled from over 50 glossaries, lists of terms and definitions, and publications that were used as primary sources, and draft EPA documents. For the most part, the terms and definitions are presented exactly as they are worded in the primary sources, with minor adjustments to reflect agreement among several definitions as to singular versus plural definitions (e.g., source versus sources) and consistent use of hyphenation, grammar tense, and American English spelling. In very limited cases, lengthy definitions were shortened by the removal of extraneous clauses and phrases (e.g., parenthetical examples of the use of a term) that were deemed as unnecessary, irrelevant, or confusing.

The terms in this Thesaurus are organized into 14 categories. The different categories are to help place the terms into context within the MRA Framework and to group terms used in different risk assessment fields. Some terms fit in more than one category. These terms are presented in the most relevant category (our determination) and when a strong case can be made for their inclusion in another category, they are cross-referenced in that section. The categories include:

- General and Framework –terms are related to how the risk assessment process is conceptualized through frameworks. General terms that are not frequently associated with one particular step in the risk assessment process are also included.
- Problem Formulation –terms are related to the problem formulation process, but may also be relevant to other steps in risk assessment
- Pathogen Characterization or Infectious Disease Hazard Characterization –general microbiology terms, terms used in pathogen characterization
- Hazard Occurrence (Pathogen Occurrence) - terms used to describe occurrence of microbes in the environment, terms relevant to environmental sampling and analysis
- Exposure – terms related to exposure, includes some terms related to dose
- Host Characterization and Health Effects– terms used in describing the effected populations, including both individual and population characteristics, such as sensitive subpopulations, terms used to characterize the health effects
- Epidemiology and surveillance – term related to epidemiological studies and clinical terms important for epidemiology, terms related to disease surveillance
- Dose-Response – terms related to dose-response, some overlap with exposure
- Modeling, Statistics, Math – terms used in quantitative modeling, statistics, general math, and uncertainty and sensitivity analysis
- Risk Characterization, Risk Management, and Policy – terms used in risk characterization, terms important for risk management and policy
- Economic – terms used in cost-benefit analysis or terms related to monetary valuation (Terms in this category are not exhaustively presented. Only terms of general interest are included.)
- Chemical – terms that are used primarily or exclusively in chemical risk assessment (Terms in this category are not exhaustively presented.)
- Ecological – terms used primarily or exclusively in ecological risk assessments (Terms in

this category are not exhaustively presented.)

- EPA – terms that are used primarily by EPA and have specific context within EPA

For each term, definitions from EPA documents are presented first, followed by additional source definitions in alphabetical order by source. Acronyms and abbreviations are included where appropriate. The order in which the definitions are presented (alphabetical) within each category should not be construed to imply any order of importance or preference. In some cases, a definition includes the use of an additional, “secondary” reference. To the extent appropriate, small differences in language for similar definitions are preserved.

Closely related terms are linked by the “Related Terms” field. This field also includes select terms that have definitions that distinguish them in particular from a contrasting term, as indicated by “*contrast with* (the relevant term).” Although this Thesaurus makes extensive use of related and contrasting term linking, such linking should not be construed as comprehensive or exhaustive. Related terms are hyperlinked within the document (indicated by blue underlining) to facilitate cross-referencing.

To look up a term, go to the alphabetical index at the end. Both the term and the page number are hyperlinked to the location of the term, so you can jump directly to the term. The category titles are included in the header on each page so you can easily determine the category under which the term is filed.

For some terms, a comment has been included to point out differences and similarities in the term definitions. Comments are presented in *italics* after the term. Terms that have multiple and/or contrasting definitions that could cause confusion or are commonly used in different contexts were presented with further discussion in Chapter 2.

CHAPTER FIVE: TERMS AND DEFINITIONS

Disclaimer: This document is a compilation of definitions from many sources within EPA and outside of EPA. This compilation is for informational purposes only. No inference should be drawn by the inclusion or exclusion in this document of any term or definition. These definitions and any associated commentary are not binding and have no legal effect as a result of their inclusion in this document; they do not constitute an EPA statute or regulation and do not substitute for such authorities. In addition, the compilation of definitions and associated commentary in this document have not been reviewed or endorsed by Agency management, and thus do not constitute official statements of EPA's views and are not binding on EPA or any party.

5.1 GENERAL AND FRAMEWORK TERMS

agent

- 1) Any physical, chemical, or biological entity that can induce an adverse response (synonymous with stressor). (EPA 1998b)
- 2) A chemical, physical, or biological entity that may cause deleterious, beneficial, or no effects to an organism after the organism is exposed to it. (EPA 2004)
- 3) The term “agent” refers generally to any chemical substance, mixture, or physical or biological entity being assessed, unless otherwise noted. (EPA 2005a)
- 4) Any physical, chemical, or biological entity that can be harmful to an organism. (EPA 2005b)
- 5) A factor, such as a microorganism, chemical substance, or form of radiation, whose presence, excessive presence, or (in deficiency diseases) relative absence is essential for the occurrence of a disease. (CDC 2005)
- 6) A chemical, biological, or physical entity that contacts a target. (IPCS 2004)

RELATED TERMS: [stressor](#)

analysis

- 1) The systematic application of specific theories and methods, including those from natural science, social science, engineering, decision science, logic, mathematics, and law, for the purpose of collecting and interpreting data and drawing conclusions about phenomena. It may be qualitative or quantitative. Its competence is typically judged by criteria developed within the fields of expertise from which the theories and methods come. (EPA 2004)
- 2) Detailed examination of anything complex, made in order to understand its nature or to determine its essential features. (IPCS/OECD 2004)

This term is used in conjunction with many other words to create multiword terms that have specific unique meanings (e.g. risk analysis, analysis plan, analysis phase).

analysis phase

A component of microbial risk assessment consisting of the technical evaluation of data concerning potential exposure and associated health effects. Elements of this process are characterization of exposure and characterization of human health effects. (ILSI 2000)

analysis plan

A plan that provides all the details of exactly how each part of the risk assessment will be performed. It usually describes in detail what analyses will be performed, how they will be performed, who will perform the work, schedules, resources, quality assurance/quality control requirements, and documentation requirements. (EPA 2004)

anecdotal data

Data based on the description of individual cases rather than controlled studies. (EPA 2003)

RELATED TERMS: [anecdotal evidence](#), [case study](#)

Additionally, anecdotal data may lack quantitative specifics and can come from sources that are not peer reviewed such as the popular media. In the epidemiology context, anecdotal data refers

specifically to case studies, but other disciplines use the term to refer to pieces of information that are based on casual observations rather than rigorous or scientific analysis.

anecdotal evidence

SEE: [anecdotal data](#), [case study](#)

animal studies

Toxicity investigations using animals. Such studies may employ animals as surrogates for humans with the expectation that the results are pertinent to humans or for investigation of effects pertinent to animals (e.g., for ecological risk assessment). (EPA 2004, EPA 2005b)

anthropogenic

Of human origin. (RAIS 2004, SRA 2004)

assessment

Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process. (IPCS/OECD 2004)

assessment endpoint

- 1) An explicit expression of the environmental value to be protected. An assessment endpoint includes both an ecological entity and specific attributes of that entity. For example, salmon are a valued ecological entity; reproduction and population maintenance (i.e., the attribute) form an assessment endpoint. (EPA 2004)
- 2) Qualitative/quantitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment. (IPCS/OECD 2004)

assessment factor

Numerical adjustment used to extrapolate from experimentally determined (dose-response) relationships to estimate the agent exposure below which an adverse effect is not likely to occur. (IPCS/OECD 2004)

RELATED TERMS: [safety factor](#), [uncertainty factor](#)

assessment questions

The questions asked during the planning/scoping phase of the risk assessment process to determine what the risk assessment will evaluate. (EPA 2004)

assumption

The thing supposed; a postulate, or proposition assumed; a supposition. (CancerWEB 2005)

attributable proportion

A measure of the public health impact of a causative factor; proportion of a disease in a group that is exposed to a particular factor which can be attributed to their exposure to that factor. (CDC 2005)

best management practice

ACRONYM: BMP

Methods that have been determined to be the most effective, practical means of preventing or reducing pollution from non-point sources. (EPA 2005b)

best professional judgment

Utilizing knowledge based on education and experience to determine the best course of action during the course of performing a risk assessment project. (EPA 2004)

RELATED TERMS: [expert judgment](#)

biologically plausible

Biologically plausible is associated with guidelines (sometimes referred to as the Bradford Hill criteria) for causal inference from epidemiological evidence. In that context, an assessment of the biological plausibility of an association demonstrated by epidemiological analysis is meant to ensure that such an association is consistent with current biological knowledge. Evidence regarding biological plausibility can never prove causality. Therefore, it is also meant to guard against attributions of causality to biologically implausible statistical associations that might result from studies that have not adequately accounted for important variables. (IOM 2002)

Can refer to both epidemiological analysis as well as theoretical biological mechanisms.

causality

The relating of causes to the effects they produce. Causes are termed necessary when they must always precede an effect and sufficient when they initiate or produce an effect. Any of several factors may be associated with the potential disease causation or outcome, including predisposing factors, enabling factors, precipitating factors, reinforcing factors, and risk factors. (CancerWEB 2005)

ceteris paribus

Latin for “other things equal.” *Ceteris paribus* clauses are nonstrict generalizations but generalizations that hold when other things are equal. They typically occur conjoined with incomplete descriptions of the factors whose presence or absence bring about an outcome. (Floridi 2003)

characterization of exposure

- 1) A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological entities. Exposure can be expressed as co-occurrence or contact, depending on the stressor and ecological component involved. (EPA 1998b)
- 2) A component of the analysis phase of microbial risk assessment that evaluates any interactions between the pathogen, the environment, and the human population. Steps in this process are pathogen characterization, determination of pathogen occurrence, and exposure analysis; the result is an exposure profile. (ILSI 2000)

characterization of human health effects

A component of the analysis phase of microbial risk assessment that evaluates the ability of a pathogenic microorganism to cause adverse human health effects under a particular set of

conditions. Steps in this process are host characterization, evaluation of human health effects, and quantification of the dose-response relationship; the result is a host-pathogen profile. (ILSI 2000)

community

The persons associated with an area who may be directly affected by area pollution because they currently live in or near the area, or have lived in or near the area in the past (i.e., current or past residents), members of local action groups, local officials, tribal governments, health professionals, and local media. Other entities, such as local industry, may also consider themselves part of the community. (EPA 2004)

Note: there are a number of other definitions of community that are especially used in ecology and human social sciences, as well as in describing microbiological relationships but they were not apparent in the documents examined in this effort.

comparative risk assessment

- 1) The process of comparing and ranking various types of risks to identify priorities and influence resource allocations. (EPA 2004)
- 2) Comparative risks can be among different pathogens and different exposures. Common metrics would provide a basis for such comparisons. (ILSI 2000 text)
- 3) An expression of the risks associated with two (or more) actions leading to the same goal; may be expressed quantitatively (a ratio of 1.5) or qualitatively (one risk greater than another risk). Any comparison among the risks of two or more hazards with respect to a common scale. (RAIS 2004, SRA 2004)

RELATED TERMS: [cumulative risk assessment](#)

conceptual model

- 1) A diagram or written description of the predicted key relationships between the stressor(s) and the assessment endpoint(s) for a risk assessment. (EPA 1997b)
- 2) A conceptual model in problem formulation is a written description and visual representation of predicted relationships between ecological entities and the stressors to which they may be exposed. (EPA 1998a)
- 3) A written description and/or a visual representation of actual or predicted relationships between humans or ecological entities and the chemicals or other stressors to which they may be exposed. (EPA 2004)
- 4) The conceptual model describes a series of working hypotheses of how the stressor might affect ecological entities. The conceptual model also describes the ecosystem potentially at risk, the relationship between measures of effect and assessment endpoints, and exposure scenarios. (CENR 1999)
- 5) A visual presentation of the proposed structure of the risk assessment model showing data needs, model outputs, and logical flow of the calculations. (FDA 2002)
- 6) A conceptual model depicts the purpose, defines the scope and scale, determines appropriate variables and identifies data needed for risk assessment. It can also serve as a preliminary or exploratory risk assessment. (ILSI 2000 text)

cumulative risk

The combined risk from aggregate exposures to multiple agents or stressors. (EPA 2004)

cumulative risk assessment

- 1) An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors. (EPA 2004)
- 2) Consideration of the total ecological risk from multiple stressors to a given eco-zone. (EPA 2005b)
- 3) (cumulative ecological risk assessment) A process that involves consideration of the aggregate ecological risk to the target entity caused by the accumulation of risk from multiple stressors. (EPA 1998a)

data integrity

Refers to security (i.e., the protection of information from unauthorized access or revision) to ensure that the information is not compromised through corruption or falsification. Data integrity is one of the constituents of data quality. (EPA 2004)

data objectivity

A characteristic indicating whether information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. Data objectivity is one of the constituents of data quality. (EPA 2004)

data quality

The encompassing term regarding the quality of information used for analysis and/or dissemination. Utility, objectivity, and integrity are constituents of data quality. (EPA 2004)

data quality objective**ACRONYM: DQO**

- 1) Qualitative or quantitative statement derived from the DQO process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support the decisions. (EPA 2004)
- 2) Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker will accept in results or decisions based on environmental data. They provide the statistical framework for planning and managing environmental data operations consistent with user's needs. (EPA 2005b)
- 3) Expectation or goal regarding the precision and accuracy of measurements, inference from data regarding distributions for inputs, and prediction of the model. (FAO/WHO 2003b)

data quality objectives process

A systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process. (EPA 2004)

data utility

Refers to the usefulness of the information to the intended users. Data utility is one of the constituents of data quality. (EPA 2004)

effect

- 1) Change in the state or dynamics of an organism, system or (sub) population caused by the exposure to an agent. (IPCS/OECD 2004)
- 2) A biological change caused by an exposure. (MERREA 2005)
- 3) The change in the average or expected value of a given response due to the change of a given factor. The change of the given factor is usually from the lowest to the highest value of those tried experimentally, and the units of the effect are usually in the same units as the response. (NIST/SEMATECH 2005b)
- 4) A biological change caused by an exposure. (RAIS 2004, SRA 2004)

effect assessment

Combination of analysis and inference of possible consequences of the exposure to a particular agent based on knowledge of the dose-effect relationship associated with that agent in a specific target organism, system or (sub) population. (IPCS/OECD 2004)

endpoint

- 1) An observable or measurable biological event or chemical concentration (e.g., metabolite concentration in a target tissue) used as an index of an effect of a chemical exposure. (EPA 2003)
- 2) (Assessment endpoint) An explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together “salmon reproduction and age class structure” form an assessment endpoint. (EPA 1998a)

RELATED TERMS: [outcome](#)

expert judgment

- 1) Opinion of an authoritative person on a particular subject. (IPCS/OECD 2004)
- 2) Judgment involves a reasoned formation of opinions. An expert is someone with special knowledge or experience in a particular problem domain. Expert judgment is documented and can be explained to satisfy outside scrutiny. (FAO/WHO 2003b)

RELATED TERMS: [best professional judgment](#)

extra risk**ACRONYM:** ER

A calculation of risk of adverse effects which adjusts for background incidence rates of the same effects, by estimating risk at dose d only among the fraction of the population not expected to respond to the secondary (background) causes: $ER = [P(d) - P(0)] / [1 - P(0)]$. For example, if the background rate ($P(0)$) = 0.8 and the response rate at dose d , $P(d)$ = 0.9, then $ER = (0.9 - 0.8) / (1 - 0.8) = 0.1 / 0.2 = 0.5$. That is, at dose d , an additional 10% of the population is expected to respond adversely. But since only 20% of the population was expected to be free of adverse

effects without the exposure of interest, this 10% represents 50% of the population that would otherwise have been unharmed by this exposure. (EPA 2003)

farm-to-table

Includes all steps involved in the production, storage, handling, distribution and preparation of a food product. (FAO/WHO 2003a)

fomite (plural; singular, fomes)

- 1) An inanimate object which, when contaminated with a viable pathogen (bacterium, virus, etc.) can transfer the pathogen to a host. (CancerWeb 2005)
- 2) Articles that convey infection to others because they have been touched. (MERREA 2005)
- 3) An inanimate object that can be the source of an infection. (Queensland Health 2005)
- 4) Objects, such as clothing, towels, and utensils that possibly harbor a disease agent and are capable of transmitting it; usually used in the plural. (Stedman 2005)

food safety objective

The maximum frequency and/or concentration of a (microbiological) hazard in a food at the time of consumption that provides the appropriate level of health protection (ALOP). Example of FSO: 100 *Listeria monocytogenes* per gram of ready-to-eat food. (CAC 2002)

gray literature

Research reports that are not found in traditional peer-reviewed publications; for example: government agency monographs, symposium proceedings, and unpublished company reports. (NLM/NICHSR 2004)

hazard

- 1) A potential source of harm. (EPA 2003)
- 2) In a general sense, “hazard” is anything that has a potential to cause harm. In risk assessment, the likelihood of experiencing a noncancer health effect is called hazard (not risk). (EPA 2004)
- 3) (a) Potential for radiation, a chemical or other pollutant to cause human illness or injury.
(b) In the pesticide program, the inherent toxicity of a compound. Hazard identification of a given substances is an informed judgment based on verifiable toxicity data from animal models or human studies. (EPA 2005b)
- 4) A source of potential harm from past, current, or future exposures. (ATSDR 2004)
- 5) A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect. (CAC 1999)
- 6) A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. A microbiological hazard is a hazard arising from bacteria, viruses, yeasts, molds and algae, parasitic protozoa and helminths, and their toxins or metabolites. (CAC 2002)
- 7) A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. (CAC 2003, FAO/WHO 2003b)
- 8) A biological, chemical or physical agent that has the potential to cause harm or loss.

(CRCWQT 2002)

- 9) A biological, chemical or physical agent in, or condition of, food with the potential to cause harm. (FAO/WHO 2003a)
- 10) Biological, chemical or physical agents with the potential to cause an adverse health effect. (FDA 2002)
- 11) Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent. (IPCS/OECD 2004)
- 12) A biological agent with the potential to cause an adverse health effect. (KIWA 2004)
- 13) A thing or action that can cause adverse effects (e.g., a human pathogen, a plant pest, an animal disease agent, the introduction of a specific commodity or product). In the OMAF framework, the term “hazard” is used to imply the cause of an adverse event and not the negative consequences. When referring to the negative consequences of a causal hazard, we encourage the use of terms such as negative outcome, consequence, or impact. (OMAF 1997)
- 14) A condition or physical situation with a potential for an undesirable consequence, such as harm to life or limb. (RAIS 2004, SRA 2004)

The definitions for hazard are in general agreement even though some are more limiting in scope than others.

hazard analysis critical control point system

ACRONYM: HACCP

- 1) A systematic methodology to control hazards in a process by applying a two-part technique: first, an analysis that identifies hazards and their severity and likelihood of occurrence; and second, identification of critical points where the hazards may be controlled, and the monitoring criteria to ensure that controls are working effectively. CRCWQT 2002
- 2) The hazard analysis critical control point system (HACCP) is a scientific and systematic way of enhancing the safety of foods from primary production to final consumption through the identification and evaluation of specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. (FAO/WHO 2003a)

RELATED TERMS: [control point](#)

hazard assessment

- 1) The process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans. (EPA 2003)
- 2) Evaluating the effects of a stressor or determining a margin of safety for an organism by comparing the concentration which causes toxic effects with an estimate of exposure to the organism. (EPA 2005b)
- 3) A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard in

contrast to risk assessment where exposure assessment is a distinct additional step. (IPCS/OECD 2004)

- 4) An analysis and evaluation of the physical, chemical and biological properties of the hazard. (RAIS 2004, SRA 2004)

hazard characterization

- 1) A description of the potential adverse health effects attributable to a specific environmental agent, the mechanisms by which agents exert their toxic effects, and the associated dose, route, duration, and timing of exposure. (EPA 2003)
- 2) The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of Microbiological Risk Assessment the concerns relate to microorganisms and/or their toxins. (CAC 1999)
- 3) The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable. (CAC 2003, FAO/WHO 2003b)
- 4) The qualitative or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents. (FDA 2002)
- 5) The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties. Hazard Characterization is the second stage in the process of Hazard Assessment, and the second step in Risk Assessment. (IPCS/OECD 2004)

RELATED TERMS: [dose-effect relationship](#), [effect assessment](#), [dose-response relationship](#), [concentration-effect relationship](#)

hazard evaluation

A component of risk evaluation that involves gathering and evaluating data on the types of health injuries or diseases that may be produced by a chemical and on the conditions of exposure under which such health effects are produced. (EPA 2005b)

hazard identification

- 1) The process of determining whether exposure to an agent can cause a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans at environmentally relevant doses. (EPA 2004)
- 2) Determining if a chemical or a microbe can cause adverse health effects in humans and what those effects might be. (EPA 2005b)
- 3) The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods. (CAC 1999, CAC 2003, FAO/WHO 2003b)
- 4) The identification of known or potential health effects associated with a particular agent. (FDA 2002)
- 5) The identification of the type and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population. Hazard identification is the

first stage in hazard assessment and the first step in the process of Risk Assessment. (IPCS/OECD 2004)

- 6) The identification of microbiological biological agents capable of causing adverse health effects and which may be present in water. (KIWA 2004)
- 7) The determination of whether a particular substance (e.g., chemical, microbiological, or physical element) or particular activity (skiing, climbing a ladder, etc.) is or is not causally linked to particular health, safety, environmental or ecological effects. Hazard identification is a qualitative description based on factors such as kind and quality of data on humans or laboratory animals, the availability of information from other studies (e.g., similarity to other chemicals, viruses or physical hazards) and the weight of the evidence from all of these data sources. (NYS 1998)
- 8) The process of determining whether exposure to an agent can cause an increase in the incidence of a health condition. (RAIS 2004, SRA 2004)

hazards analysis

Procedures used to (1) identify potential sources of release of hazardous materials from fixed facilities or transportation accidents; (2) determine the vulnerability of a geographical area to a release of hazardous materials; and (3) compare hazards to determine which present greater or lesser risks to a community. (EPA 2005b, RAIS 2004)

host characterization

Evaluation of the characteristics of a potentially exposed human population that may influence susceptibility to a particular pathogen. (ILSI 2000)

host pathogen profile

A qualitative and/or quantitative evaluation of the nature and potential magnitude of human health effects associated with specific pathogen exposure. (ILSI 2000)

human exposure evaluation

Describing the nature and size of the population exposed to a substance and the magnitude and duration of their exposure. (EPA 2005b)

input

That which is put in or taken in, or which is operated on or utilized by any process or system (either material or abstract), e.g., the information that is put into a model. (FAO/WHO 2003b)

iterative process

The risk assessment process is not linear, but fluid and dynamic. During any of the three phases of risk assessment, problem formulation, analysis, and risk characterization, other phases might be revisited and refined. (ILSI 2000 text)

laboratory studies

Research carried out in a laboratory (e.g., testing chemical substances, growing tissues in cultures, or performing microbiological, biochemical, hematological, microscopical, immunological, parasitological tests). (EPA 2004)

methods

A systematic procedure or mode of inquiry used in microbial risk assessment. (ILSI 2001)

Note: methods are also used in a number of other microbiological contexts such as specific analytical processes, protocols for conducting scientific procedures, and for various disciplinary approaches in microbiology.

multipathway assessment

An assessment that considers more than one exposure pathway. For example, evaluation of exposure through both inhalation and ingestion would be a multipathway assessment. Another example would be evaluation of ingestion of contaminated soil and ingestion of contaminated food. (EPA 2004)

RELATED TERMS: [multipathway exposure](#), [multipathway risk](#)

population

- 1) An aggregate of individuals of a species within a specified location in space and time. (EPA 1998a)
- 2) A group of interbreeding organisms occupying a particular space; the number of humans or other living creatures in a designated area. (EPA 2005b)
- 3) A group or number of people living within a specified area or sharing similar characteristics (such as occupation or age). (ATSDR 2004)
- 4) The total number of inhabitants of a given area or country. In sampling, the population may refer to the units from which the sample is drawn, not necessarily the total population of people. (CDC 2005)
- 5) All the inhabitants of a given country or area considered together; the number of inhabitants of a given country or area. *Sampling*: the whole collection of units from which a sample may be drawn; not necessarily a population of persons; the units may be institutions, records, or events. The sample is intended to give results that are representative of the whole population. (Last 1983)
- 6) All the inhabitants of a given country or area considered together; the number of inhabitants of a given country or area. (MERREA 2005)
- 7) A population is any entire collection of people, animals, plants or things from which one may collect data. It is the entire group one is interested in, which one wishes to describe or draw conclusions about. In order to make any generalizations about a population, a sample, that is meant to be representative of the population, is often studied. For each population there are many possible samples. A sample statistic gives information about a corresponding population parameter. For example, the sample mean for a set of data would give information about the overall population mean. It is important that the investigator carefully and completely defines the population before collecting the sample, including a description of the members to be included. (STEPS 1997)

RELATED TERMS: [parameter](#); *contrast with* [sample](#)

preliminary assessment

The process of collecting and reviewing available information about a known or suspected waste site or release. (EPA 2005b)

probabilistic risk analysis

- 1) Calculation and expression of health risks using multiple risk descriptors to provide the likelihood of various risk levels. Probabilistic risk results approximate a full range of possible outcomes and the likelihood of each, which often is presented as a frequency distribution graph, thus allowing uncertainty or variability to be expressed quantitatively. (EPA 2004)
- 2) Probabilistic analysis - Analysis in which distributions are assigned to represent variability or uncertainty in quantities. The form of the output of a probabilistic analysis is likewise a distribution. (FAO/WHO 2003b)

RELATED TERMS: [probabilistic risk assessment](#)

probabilistic risk assessment

SEE: [probabilistic risk analysis](#)

problem formulation

- 1) In ecological risk assessment, the initial stage of a risk assessment where the purpose of the assessment is articulated, assessment endpoints and a conceptual model are developed, and a plan for analyzing and characterizing risk is determined. (EPA 2004)
- 2) In microbial assessment, a systematic planning step that identifies the goals, breadth, and focus of the microbial risk assessment, the regulatory and policy context of the assessment, and the major factors that will need to be addressed for the assessment. (ILSI 2000)

RELATED TERMS: [planning and scoping](#)

problem statement

A statement of the perceived problem to be studied by the risk assessment. Problem statements often also include statements about how the problem is going to be studied. (EPA 2004)

qualitative data

Observations or information characterized by measurement on a categorical scale, i.e., a dichotomous or nominal scale, or, if the categories are ordered, an ordinal scale. Examples are sex, hair color, death or survival, and nationality. (Last 1983)

qualitative risk assessment

- 1) A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk. (CAC 1999, FAO/WHO 2003b)
- 2) Risk assessment that is based on qualitative data or giving a qualitative result. The results are often stated in an estimated range, such as “there is a moderate to high risk of a certain outcome occurring.” (FDA 2001)

quantitative risk assessment

- 1) A risk assessment that provides numerical expressions of risk and indication of the

attendant uncertainties. (EC 1995)

- 2) Risk assessment that uses modeling to determine the probability(s) of what can go wrong, how likely it is to happen, and how severe is the health impact. The results are stated in numerical terms, such as “there is a 42% probability that one illness may occur from eating a serving of X food with a certain health outcome.” (FDA 2001)

refined method

This method is intended to provide accurate exposure and risk using appropriately rigorous and scientifically credible methods. The purpose of such methods, models or techniques is to produce an accurate and precise estimate of exposure or risk, or both, consistent with data quality objectives or best practice, or both. (FAO/WHO 2003b)

risk

- 1) In the context of human health, the probability of adverse effects resulting from exposure to an environmental agent or mixture of agents. (EPA 2003)
- 2) In the context of human health, the probability of injury, disease, or death from exposure to a chemical agent or a mixture of chemicals. In quantitative terms, risk is expressed in values ranging from zero (representing the certainty that harm will not occur) to one (representing the certainty that harm will occur). (EPA 2004)
- 3) A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard. (EPA 2005b)
- 4) A measure of the chance that damage to life, health, property, or the environment will occur. (EPA 2005e)
- 5) The probability that something will cause injury or harm. (ATSDR 2004)
- 6) A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. (CAC 1999, 2003, FAO/WHO 2003b)
- 7) A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. A microbiological risk is a risk arising from the presence in food of bacteria, viruses, yeasts, molds and algae, parasitic protozoa and helminths, and their toxins or metabolites. (CAC 2002)
- 8) The probability that an event will occur, e.g., that an individual will become ill or die within a stated period of time or age. (CDC 2005)
- 9) The probability of a specified hazard causing harm. (CRCWQT 2002)
- 10) The likelihood of the occurrence and the magnitude of the consequences of exposure to a hazard on human health. (FDA 2002)
- 11) The product of the likelihood of the occurrence and the magnitude of the consequences of exposure to a pathogen on human health. (ILSI 2000)
- 12) The probability of an adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent. (IPCS/OECD 2004)
- 13) The likelihood of occurrence of an adverse health effect consequent to a hazard in drinking water. (KIWA 2004)
- 14) The possibility of an adverse outcome and the likelihood and probability of its occurrence. (NYS 1998)
- 15) The probability that an individual will develop disease (or experience an event) in a specified period of time. Estimated by the cumulative incidence. (NZ 2002)

- 16) The likelihood of the occurrence and the magnitude of the consequences of an adverse event; a measure of the probability of harm and the severity of impact of a hazard. In the OMAF framework the term “risk” is always used to imply elements of probability and impact. We discourage the use of the term “risk” to imply only the probability component of risk. When referring to the probability component of risk we encourage the use of terms such as probability, likelihood, or frequency. (OMAF 1997)
- 17) The product of: impact of severity (consequence) and impact of likelihood (probability). Specifically for carcinogenic effects, risk is estimated as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to a potential carcinogen. Specifically for noncarcinogenic (systemic) effects, risk is not expressed as a probability but rather is evaluated by comparing an exposure level over a period of time to a reference dose derived for a similar exposure period. (RAIS 2004)
- 18) The potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence of the event given that it has occurred. (SRA 2004)
- 19) The probability of an adverse event occurring. (USDA 2004)

RELATED TERMS: [hazard](#)

The ILSI and the Codex definitions are similar in that they recognize the relationship between the probability and the magnitude of an outcome in determining risk; however, ILSI characterizes a risk as neutral, while Codex limits the health effects to negative ones (“adverse” and “severity”). ILSI and Codex definitions also differ in that ILSI does not limit the vehicle of exposure to food, as Codex does, although both organizations limit the causal event to a “pathogen” (generally, but not always, used to indicate a microbe).

risk analysis

- 1) A process consisting of three components: risk assessment, risk management and risk communication. (CAC 1999 2002, 2003, FAO/WHO 2003a,b, FDA 2002)
- 2) A process for controlling situations where an organism, system or (sub) population could be exposed to a hazard. The risk analysis process consists of three components: risk assessment, risk management and risk communication. (IPCS/OECD 2004)
- 3) A detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks. (MERREA 2005, RAIS 2004, SRA 2004)
- 4) The process that includes risk assessment, risk management, and risk communication. (OMAF 1997)

risk assessment

- 1) In the context of human health, the evaluation of scientific information on the hazardous properties of environmental agents (hazard characterization), the dose-response relationship (dose-response assessment), and the extent of human exposure to those agents (exposure assessment). The product of the risk assessment is a statement

- regarding the probability that populations or individuals so exposed will be harmed and to what degree (risk characterization). (EPA 2003)
- 2) For air toxics, the scientific activity of evaluating the toxic properties of a chemical and the conditions of human or ecological exposure to it in order both to ascertain the likelihood that exposed humans or ecological receptors will be adversely affected, and to characterize the nature of the effects they may experience. (EPA 2004)
 - 3) Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants.(EPA 2005b)
 - 4) A methodology used to examine all possible risks involved with a particular product or organism. Risk assessment can be divided into four parts: identification of hazards; dose response (how much exposure causes particular problems (i.e., cancer, convulsions, death); exposure assessment (determining how much exposure will be received by people during particular activities); and risk characterization (determining a probability that a risk will occur). (EPA 2005e)
 - 5) A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. (CAC 1999, 2002, 2003, FAO/WHO 2003a,b)
 - 6) The scientific evaluation of known or potential adverse health effects resulting from human exposure to hazards. The process consists of the following steps: hazard identification, exposure assessment, hazard characterization (dose-response), and risk characterization. (FDA 2002)
 - 7) The process of identifying and measuring the risk resulting from a specific use or occurrence of a chemical. Risk assessment takes into account the possible harmful effects on people of using the chemical in the way that is proposed and all the possible routes of exposure. (FSA 2005)
 - 8) When referring to a microbial risk assessment, a process that evaluates the likelihood of human health effects occurring after exposure to a pathogenic microorganism or to a medium in which pathogens exist. (ILSI 2000)
 - 9) A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterisation (related term: dose-response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process. (IPCS/OECD 2004)
 - 10) A systematic approach to organizing and analyzing data, scientific knowledge, and other information to identify possible adverse human health or environmental effects which may occur because of exposure to an agent (chemical, microbiological, or physical substance) or an activity (skiing, climbing a ladder, etc.). It also estimates the likelihood of the effect occurring under specified conditions. A risk assessment generally has four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. (NYS 1998)
 - 11) The process of identifying a hazard and characterizing the risk presented by that hazard, in qualitative or quantitative terms. (OMAF 1997)

- 12) The process of establishing information regarding acceptable levels of a risk and/or levels of risk for an individual, group, society, or the environment. (RAIS 2004, SRA 2004)

risk assessment policy

- 1) Elaboration of guidelines for the choice of options and associated judgments as well as for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained. (CAC 2002)
- 2) Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained. (CAC 2003)

risk assessment work plan

A document that outlines the specific methods to be used to assess risk, and the protocol for presenting risk results. The risk assessment work plan may consist of one document or the compilation of several work plans that, together, constitute the overall risk assessment work plan. (EPA 2004)

risk assessor

- 1) The person or group of people responsible for conducting a qualitative and quantitative evaluation of the risk posed to human health and/or the environment by environmental pollutants. (EPA 2004)
- 2) Member of team of interdisciplinary group of professionals, responsible for conducting the risk assessment. Includes individuals knowledgeable and experienced in the risk assessment process, provides specific technical expertise, mathematical modeler. (FDA 2002)

risk characterization

- 1) Integrates exposure and stressor-response to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. (EPA 1998a)
- 2) The integration of information on hazard, exposure, and dose-response to provide an estimate of the likelihood that any of the identified adverse effects will occur in exposed people. (EPA 2003)
- 3) The last phase of the risk assessment process in which the information from the toxicity and exposure assessment steps are integrated and an overall conclusion about risk is synthesized that is complete, informative and useful for decision-makers. In all cases, major issues and uncertainty and variability associated with determining the nature and extent of the risk should be identified and discussed. The risk characterization should be prepared in a manner that is clear, transparent, reasonable, and consistent. (EPA 2004)
- 4) The last phase of the risk assessment process that estimates the potential for adverse health or ecological effects to occur from exposure to a stressor and evaluates the uncertainty involved. (EPA 2005b)
- 5) The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment. (CAC 1999, 2002, 2003; FAO/WHO

- 2003b)
- 6) The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment. (FAO/WHO 2003a)
 - 7) Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties. (FDA 2002)
 - 8) In a microbial risk assessment, estimation of the likelihood of adverse human health effects occurring as a result of a defined exposure to a microbial contaminant or medium. (ILSI 2000)
 - 9) The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions. Risk characterization is the fourth step in the risk assessment process. (IPCS/OECD 2004)
 - 10) The qualitative and quantitative estimation, including attendant uncertainties of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment. (KIWA 2004)
 - 11) The description of the nature and the magnitude of the health, safety, or environmental risk, including attendant uncertainties. Often, comparisons will be made to everyday risk occurrences (death from a car accident, being struck by lightning, etc.) to help characterize the risk and make it more understandable to the general public. (NYS 1998)
 - 12) The process within risk assessment, of estimating the probability of harm and the severity of impact of an identified hazard, and describing attendant uncertainty. (OMAF 1997)
 - 13) This last step in the risk assessment process characterizes the potential for adverse health effects and evaluates the uncertainty involved. (RAIS 2004)

There is agreement that the term risk characterization should refer to the final step of the risk assessment process. In some cases, some of the more specific requirements of risk characterization are spelled out. For example, transparency is a specific requirement mentioned in the EPA Air Toxics Risk Assessment Library. Transparency is not specifically mentioned in the other definitions, but other frameworks for risk assessment include a general requirement for transparency. The EPA-ILSI Framework (ILSI 2000) and the EPA Risk Characterization Handbook (EPA 100-B-00-002) include many risk management concepts. The Codex framework (CAC 1999) specifically excludes risk management from risk characterization.

risk communication

- 1) The exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, and other stakeholders. (EPA 2004)
- 2) The exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, interest groups, etc. (EPA 2005b, RAIS 2004)
- 3) The process of exchanging information about levels or significance of health or environmental risk. (EPA 2005e)

- 4) The exchange of information to increase understanding of health risks. (ATSDR 2004)
- 5) The interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties. (CAC 1999)
- 6) The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk related factors and risk perception among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. (CAC 2002, 2003, FAO/WHO 2003b)
- 7) The interactive exchange of information and opinions concerning risks among risk assessors, risk managers, consumers and other interested parties. (FAO/WHO 2003a)
- 8) The interactive exchange of information and opinions concerning risk and risk management among risk assessors, managers, consumers, industry, and other interested parties. (FDA 2002)
- 9) Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups and the general public. (IPCS/OECD 2004)
- 10) The open exchange of information and opinion, leading to a better understanding of risk and risk related decisions. (OMAF 1997)

risk description

Risk description is the step in risk characterization where the event is described according to its nature, severity, and consequences. (ILSI 2000 text)

risk difference

SEE: [additional risk](#)

risk estimate

- 1) A description of the probability that organisms exposed to a specific dose of a chemical or other pollutant will develop an adverse response, e.g., cancer. (EPA 2005b)
- 2) Output of risk characterization. (CAC 1999, FAO/WHO 2003b)
- 3) The quantitative estimation of risk resulting from risk characterization. (CAC 2003)
- 4) Risk estimation describes the types and magnitude of effects anticipated from exposure to the microbe or medium and can be qualitative or quantitative depending on the data and methods used. (ILSI 2000text)
- 5) Quantification of the probability, including attendant uncertainties, that specific adverse effects will occur in an organism, system or (sub)population due to actual or predicted exposure. (IPCS/OECD 2004)
- 6) The scientific determination of the characteristics of risks, usually in as quantitative a way as possible. These include the magnitude, spatial scale, duration, and intensity of adverse consequences and their associated probabilities as well as a description of the cause and effect links. (RAIS 2004, SRA 2004)

risk evaluation

- 1) Establishment of a qualitative or quantitative relationship between risks and benefits of

exposure to an agent, involving the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the agent. It is an element of risk management. Risk evaluation is synonymous with risk-benefit evaluation. (IPCS/OECD 2004)

- 2) A component of risk assessment in which judgments are made about the significance and acceptability of risk. (MERREA 2004, RAIS 2004, SRA 2004)

risk factor

- 1) Characteristic (e.g., race, sex, age, obesity) or variable (e.g., smoking, occupational exposure level) associated with increased probability of a toxic effect. (EPA 2005b, RAIS 2004)
- 2) A characteristic (e.g., race, sex, age, obesity) or variable (e.g., smoking, exposure) associated with increased chance of toxic effects. Some standard risk factors used in general risk assessment calculations include average breathing rates, average weight, and average human life span. (EPA 2005e)
- 3) An aspect of personal behavior or lifestyle, an environmental exposure, or an inborn or inherited characteristic that is associated with an increased occurrence of disease or other health-related event or condition. (CDC 2005)
- 4) Anything that increases the likelihood of disease, injury, illness, death, etc. (NYS 1998)
- 5) A cause, or indicator of a cause, of disease. (NZ 2002)

risk identification

Recognizing that a hazard exists and trying to define its characteristics. Often risks exist and are even measured for some time before their adverse consequences are recognized. In other cases, risk identification is a deliberate procedure to review, and it is hoped, anticipate possible hazards. (RAIS 2004, SRA 2004)

risk management

- 1) In the context of human health, a decision making process that accounts for political, social, economic and engineering implications together with risk-related information in order to develop, analyze and compare management options and select the appropriate managerial response to a potential chronic health hazard. (EPA 2003)
- 2) The decision-making process that uses the results of risk assessment to produce a decision about environmental action. Risk management includes consideration of technical, scientific, social, economic, and political information. (EPA 2004)
- 3) The process of evaluating and selecting alternative regulatory and non-regulatory responses to risk. The selection process necessarily requires the consideration of legal, economic, and behavioral factors. (EPA 2005b, RAIS 2004)
- 4) The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. (Control in this case is defined as prevention, elimination, or reduction of hazards and/or minimization of risks.) (CAC 1999, USDA 2004)
- 5) The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment when available and

other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, selecting appropriate prevention and control options. This process can be managed at the national, regional or international level. (CAC 2002)

- 6) The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options. (CAC 2003, FAO/WHO 2003b)
- 7) The systematic evaluation of the water supply system, the identification of hazards and hazardous events, the assessment of risks, and the development and implementation of preventive strategies to manage the risks. (CRCWQT 2002)
- 8) The process of weighing policy alternatives in the light of results of risk assessment, and, if required, selecting and implementing appropriate control options, including regulatory measures. (FAO/WHO 2003a)
- 9) The process of weighing policy alternatives in light of results or risk assessment, and, if required, selecting and implementing appropriate control options, including regulatory measures. (FDA 2002)
- 10) Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyze, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation, emission and exposure control, risk monitoring. (IPCS/OECD 2004)
- 11) The process of integrating the results of a risk assessment with other information to make decisions about the need for, method of, and extent of risk reduction. Policy considerations and statutory requirements can dictate the extent to which risk information is used in decision-making and the extent to which other factors-such as technical feasibility, cost, and offsetting benefits-play a role. (NYS 1998)
- 12) The process of identifying, evaluating, selecting and implementing alternatives for mitigating risk. (OMAF 1997)

risk manager

- 1) The person or group responsible for evaluating and selecting alternative regulatory and non-regulatory responses to risk. (EPA 2004)
- 2) The representative of government at a national level or regional level or representative of international organization at the international level who has the responsibility of risk management. (CAC 2002)
- 3) A decision maker; individuals or group responsible for taking actions to control, reduce, or mitigate an identified hazard. (FDA 2002)

risk-benefit analysis

Determining and weighing the relative risks and benefits of taking a certain action. It includes determining who receives the risks and benefits. (Navy 2002)

safe

Condition of exposure under which there is a practical certainty that no harm will result to exposed individuals. (EPA 2005b)

safety

- 1) Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances. It is the reciprocal of risk. (IPCS/OECD 2004)
- 2) A judgment of the acceptability of risk (a measure of the probability of an adverse outcome and its severity) associated with using a technology in a given situation, e.g., for a patient with a particular health problem, by a clinician with certain training, or in a specified treatment setting. (NLM/NICHSR 2004)
- 3) Relative protection from adverse consequences. (RAIS 2004, SRA 2004)

safety factor

Composite (reductive) factor by which an observed or estimated no-observed-adverse effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. (IPCS/OECD 2004)

RELATED TERMS: [assessment factor](#), [uncertainty factor](#)

safety limits

Limits set by expert committees, for all approved pesticides, of the level of exposure that will not harm people's health. (FSA 2005)

source

- 1) An entity or action that releases a stressor to the environment (or imposes a stressor on the environment). (EPA 1998a)
- 2) A place where pollutants are emitted, for example, a chimney stack. (RAIS 2004, SRA 2004)
- 3) The origin of an agent for the purposes of an exposure assessment. (IPCS 2004)

stakeholder

- 1) Any organization, governmental entity, or individual that has a stake in or may be impacted by a given approach to environmental regulation, pollution prevention, energy conservation, etc. (EPA 2005b)
- 2) A person, group, or community who has an interest in activities at a hazardous waste site. (ATSDR 2004)
- 3) Any individual, group or organization that may affect, be affected by, or perceive itself to be affected by the risk or risk management activities. (CAC 2002)

stepwise approach

A stepwise approach includes a preliminary qualitative assessment of health and exposure before a quantitative risk assessment is pursued. The stepwise approach is used to prioritize resources, define the scope and to determine if adequate information is available for quantitative risk assessment. It is a feature of problem formulation. (ILSI 2000 text)

surrogate

Something that serves as a substitute. In risk analysis, surrogates are often used when data on the item of interest (a chemical, an industry, an exposure, etc.) is lacking. As an example, underground mining of coal and hardrock minerals can be used as a surrogate for underground oil shale mining. (RAIS 2004, SRA 2004)

RELATED TERMS: [indicator](#)

surrogate data

- 1) Data from studies of test organisms or a test substance that are used to estimate the characteristics or effects on another organism or substance. (EPA 2005b)
- 2) Substitute data or measurements on one quantity used to estimate analogous or corresponding values for another quantity. (FAO/WHO 2003b)

tiered analysis

An analysis arranged in layers/steps. Risk assessments/analyses are often conducted in consecutive layers/steps that begin with a reliance on conservative assumptions and little data (resulting in less certain, but generally conservative answers) and move to more study area specific data and less reliance on assumptions (resulting in more realistic answers). The level of effort and resources also increases with the development of more realistic data. (EPA 2004)

tools of microbial risk assessment

Techniques for conducting microbial risk assessment, which can be classified into three groups: qualitative, semiquantitative, and quantitative. (ILSI 2000)

transparency

- 1) Conducting a risk assessment in such a manner that all of the scientific analyses, uncertainties, assumptions, and science policies which underlie the decisions made throughout the risk assessment are clearly stated (i.e., made readily apparent). (EPA 2004)
- 2) For risk assessment to be transparent, methods, and assumptions should be clearly stated and understandable to the intended audience, so that the audience is able to evaluate the adequacy of the data and methods. (ILSI 2000 text)

The criteria by which adequate transparency is judged should include the intended audience because transparency for other risk assessors in the field is quite different than transparency designed for the general public. The purpose for the transparency may or may not be stated and can range from general review of the approach and assumptions to detailed information that would be required if the model or input data needed to be updated or replicated.

transparent

Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgments, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review. (CAC 1999, FAO/WHO 2003b)

water quality

A description of the chemical, physical and biological characteristics of water for a particular

purpose. (CRCWQT 2002)

5.2 PROBLEM FORMULATION TERMS

planning and scoping

The process of determining the purpose, scope, players, expected outcomes, analytical approach, schedule, deliverables, QA/QC, resources, and document requirements for the risk assessment. (EPA 2004)

RELATED TERMS: [problem formulation](#)

resources

Money, time, equipment, and personnel available to perform the assessment. (EPA 2004)

Note: environmental resources may also be considered such as air, water, soil, minerals, etc. and are important factors in defining the media of concern with respect to human exposure to microorganisms.

scenario

A construct characterizing the likely pathway affecting the safety of the food product. This may include consideration of processing, inspection, storage, distribution, and consumer practices. Probability and severity values are applied to each scenario. (FAO/WHO 1995)

scenario uncertainty

Uncertainty due to descriptive errors, aggregation errors, errors in professional judgment, or incomplete analysis. (EPA 2004)

screening-level risk assessment

A risk assessment performed with few data and many conservative assumptions to identify exposures that should be evaluated more carefully for potential risk. (EPA 2004, 2005b)

screening method

This method is intended to provide conservative overestimates of exposure and risk using relatively simple and quick calculation methods and with relatively low data input requirements.

The purpose of such methods, models or techniques is to eliminate the need for further, more detailed modeling for scenarios that do not cause or contribute to high enough levels of exposure or risk to be of potential concern. If a screening method indicates that levels of exposure or risk are low, then there should be high confidence that actual exposures or risk levels are low. Conversely, if a screening method indicates that estimated exposure or risk levels are high, then a more refined method should be applied since the screening method is intentionally biased. (FAO/WHO 2003b)

RELATED TERMS: [refined method](#)

systematic review

A form of structure literature review that addresses a question that is formulated to be answered by analysis of evidence, and involves objective means of searching the literature, applying predetermined inclusion and exclusion criteria to this literature, critically appraising the relevant literature, and extraction and synthesis of data from evidence base to formulate findings. (NLM/NICHSR 2004)

RELATED TERMS: [meta-analysis](#)

time profile

A continuous record of instantaneous values over a time period (e.g., exposure, dose, medium intake rate). (IPCS 2004)

5.3 PATHOGEN CHARACTERIZATION OR INFECTIOUS DISEASE HAZARD CHARACTERIZATION TERMS

agent of disease

A factor, such as a microorganism, chemical substance, or form of radiation, whose presence, excessive presence, or (in deficiency diseases) relative absence is essential for the occurrence of a disease. A disease may have a single agent, a number of independent alternative agents (at least one of which must be present), or a complex of two or more factors whose combined presence is essential for the development of the disease. See also causality. (Last 1983)

amplification

Multiplication or replication of a microorganism within a given medium. (ILSI 2000)

anaerobic

Anaerobic processes or organisms do not use oxygen. The term anaerobic can also refer to an oxygen-free environment. (Jones 2006)

anti-microbial

An agent that kills microbes. (EPA 2005b)

This term is sometimes more broadly applied to agents that slow microbial growth or inactivate microbial functions. Antibiotics, antiseptics, disinfectants, and biocides are all anti-microbial.

attenuated (strain)

- 1) To reduce the virulence (infectivity) of a pathogenic microorganism. (CancerWeb 2005)

RELATED TERMS: [strain](#)

avirulent

- 1) Not virulent. (CancerWeb 2005, Stedman 2005)
- 2) Avirulent mutants of a bacterium or virus have lost the capacity to infect a host productively, that is, to make more bacterium or virus. (Jones 2006)

bacteria

- 1) Singular: bacterium. Microscopic single-celled organisms with rigid walls. Bacteria are found almost everywhere. Some bacteria in soil, water or air can cause human disease. (CRCWQT 2002)
- 2) Single-cell, independently replicating microorganisms that lack a membrane-bound nucleus and other organelles. (FDA 2001)
- 3) One-celled microorganisms that are either free-living or parasitic, some of which may cause illness in humans and/or animals. (USDA 2004)

bactericidal

- 1) Capable of killing bacteria. Some antibiotics are either bacteriocidal or bacteriostatic in their action. (CancerWeb 2005)
- 2) Causing the death of bacteria. (Stedman 2005)
- 3) A treatment is said to be bacteriocidal when it causes the death of bacterial cells. (Jones

2006)

biological contaminant

- 1) Living organisms or derivatives (e.g. viruses, bacteria, fungi, and mammal and bird antigens) that can cause harmful health effects when inhaled, swallowed, or otherwise taken into the body. (EPA 2005b)

RELATED TERMS: [contaminant](#)

coliforms

- 1) A group of bacteria found in the intestines of animals (including humans), and also in soil, vegetation, and water. (CRCWQT 2002)
- 2) The most common form of bacteria found in untreated water. The presence of this group of non-pathogenic bacteria in drinking water is an indicator that the water may be contaminated by sewage and/or other similar material and should not be ingested. Fecal coliform bacteria, of which *E. coli* is one type, live in the intestines of warm-blooded animals. Pathogenic coliforms can cause diarrhea and other serious health problems if the bacteria are ingested. (FDA 2001)

RELATED TERMS: [bacteria](#), [indicator](#), [indicator organisms](#)

colonization

- 1) The formation of compact population groups of the same type of microorganism, as the colonies that develop when a bacterial cell begins reproducing. (CancerWeb 2005, Stedman 2005)
- 2) The process in which microorganisms live and reproduce in or on either the human body without causing disease, or an inanimate object such as a disinfection machine (Queensland Health 2005)
- 3) Implantation and growth of a microorganism on a host. (USDA 2004)

colony forming unit

ACRONYM: cfu, CFU

- 1) An individual cell which is able to clone itself into an entire colony of identical cells. (CancerWeb 2005)
- 2) Unit of measurement for viable bacteria numbers. (USDA 2004)

commensal (commensalism)

- 1) Living on or within another organism and deriving benefit without injuring or benefiting the other individual. An organism living on or within another, but not causing injury to the host. A type of symbiosis where two (or more) organisms from different species live in close proximity to one another, in which one member is unaffected by the relationship and the other benefits from it. (CancerWeb 2005)
- 2) Pertaining to or characterized by commensalism. An organism participating in commensalism. (Stedman 2005)
- 3) A symbiotic relationship in which one species benefits while the other is unaffected. (Jones 2006)

contagious

- 1) Capable of being transmitted from one person to another by contact or close proximity. (CDC 2005)
- 2) Transmitted by contact; in common usage, “highly infectious.” (MERREA 2005)

RELATED TERMS: [infectiousness](#), [infectivity](#), [transmissible](#)

contaminant

- 1) A substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects. (ATSDR 2004)
- 2) Any physical, chemical, biological, or radiological substance or matter that has an adverse effect. (CRCWQT 2002)

contamination

Contact with an admixture of an unnatural agent, with the implication that the amount is measurable. The deposition of unwanted radioactive material on the surfaces of structures, areas, objects, or people. It may also be airborne, external, or internal (inside components or people). (RAIS 2004)

culture

In microbiology, the growth of an organism in or on a nutrient medium. (MERREA 2005)

emerging pathogens

An illness-causing microorganism that is either:

- previously unknown to be a human pathogen;
- not expected to occur in a particular food;
- has caused a dramatic increase in new cases of illness. (FDA 2001)

etiologic

Cause of disease/illness, as in the etiology of smallpox is the variola virus. (MERREA 2005)

exponential growth (rate)

- 1) A rate of growth of an organism, a part of an organism, or a population of organisms which, when graphed, produces an exponential or logarithmic curve. Such a rate occurs, for example: during the exponential growth phase, when a population of bacterial (or other) cells divide at a constant rate so that the total number of cells doubles with each division. (CancerWeb 2005).
- 2) A period in the course of growth of a bacterial culture in which maximal multiplication is occurring by geometrical progression; thus, if the logarithms of their numbers are plotted against time, they will form a straight upward line. (Stedman 2005)

fecal coliform

- 1) Bacteria found in the intestinal tracts of mammals, this bacteria in water or sludge is an indicator of pollution and possible contamination by pathogens. (EPA 2005e)
- 2) A subgroup of bacteria of the coliform type that live mainly in the gut of warm-blooded animals. The detection of fecal coliforms in water is an indication of poor water quality

and the possibility of pathogenic organisms being present. (CRCWQT 2002)

RELATED TERMS: [coliforms](#), [indicator](#), [indicator organisms](#)

flora

- 1) Intestinal flora: The various bacteria that normally live in the intestinal tract. Normal intestinal flora are important to aid in the breakdown of certain foods for absorption. (CancerWeb 2005)
- 2) The population of microorganisms inhabiting the internal and external surfaces of healthy conventional animals. (Stedman 2005)

food ecology

The study of the interactions between factors inherent (pH, water activity, nutrients) in or external (temperature, gaseous environment) to a food and the composition of its specific microbial population. (ILSI 2000)

foodborne pathogen

A microorganism that is capable of causing disease and that is transmissible by ingestion of food. (ILSI 2000)

frank pathogen

A microorganism capable of producing disease in both healthy and compromised persons. (ILSI 2000)

RELATED TERMS: [opportunistic pathogen](#)

fungi (fungus)

- 1) Molds, mildews, yeasts, mushrooms, and puffballs, a group of organisms lacking in chlorophyll (i.e., are not photosynthetic) and which are usually non-mobile, filamentous, and multicellular. Some grow in soil, others attach themselves to decaying trees and other plants whence they obtain nutrients. Some are pathogens, others stabilize sewage and digest composted waste. (EPA 2005b)
- 2) Funguses, or fungi, are types of plants that have no leaves, flowers or roots. Both words, funguses and fungi, are the plural of fungus. (EPA 2005e)
- 3) Fungi includes organisms such as slime molds, mushrooms, smuts, rusts, mildews, moulds, stinkhorns, puffballs, truffles and yeasts. All are classified in this kingdom because they absorb food in solution directly through their cell walls and reproduce through spores. None conduct photosynthesis. (CancerWeb 2005)
- 4) Simple plants called "Saprophytes" that lack chlorophyll (the green coloring that plants use to make food). Because fungi lack chlorophyll, they cannot produce their own food. Therefore, they must take carbohydrates, proteins, and other nutrients from the animals, plants, or decaying matter on which they live. (FDA 2001)
- 5) A division of eukaryotic organisms that grow in irregular masses, without roots, stems, or leaves, and are devoid of chlorophyll or other pigments capable of photosynthesis. Each organism (thallus) is unicellular to filamentous, and possesses branched somatic structures (hyphae) surrounded by cell walls containing glucan or chitin or both, and containing true nuclei. They reproduce sexually or asexually (spore formation), and may

obtain nutrition from other living organisms as parasites or from dead organic matter as saprobes (saprophytes). Relatively few fungi are pathogenic for humans, whereas most plant diseases are caused by fungi. (Stedman 2005)

host specificity

The characteristic of a pathogen that renders it capable of infecting one or more specific hosts. (ILSI 2000)

independent action

The mean probability of infection per inoculated microorganism is independent of the number of organisms in the inoculum (disease). (Meynell and Stocker 1957)

RELATED TERMS: Contrast with [quorum sensing](#)

indicator

- 1) In biology, any biological entity or processes, or community whose characteristics show the presence of specific environmental conditions. In chemistry, a substance that shows a visible change, usually of color, at a desired point in a chemical reaction. A device that indicates the result of a measurement; e.g. a pressure gauge or a moveable scale. (EPA 2005b)
- 2) There are limitation and assumptions associated with using a single pathogen as a representative for a class of pathogens or a nonpathogenic indicator species for a pathogen of pathogen group. Surrogate and indicator are synonymous. (ILSI 2000 text)

RELATED TERMS: [coliforms](#), [surrogate](#), [indicator organisms](#)

*The term indicator is used in a several ways. In the ecological context it refers to a species that indicates the overall state of the local ecosystem. Indicator is also used in the general sense to mean anything that can be correlated with the presence of the hazard. For example, fecal sterols can be an indicator of fecal material. In this case the assumption is that fecal material presents a hazard due to the presence of human pathogens. The most common use of indicator in the context of microbial risk assessment is indicator bacteria, which are bacteria whose presence indicates the presence of fecal material. An indicator may be linked directly to a health outcome through epidemiology. For example, the presence of the indicator bacteria, *E. coli*, in recreational water can be statistically linked to an increase in gastrointestinal illness in swimmers.*

indicator, fecal

A microbiological organism (e.g., *E. coli*), or group of organisms (e.g., fecal coliforms), that is commonly and specifically associated with fecal material or illness risk among bathers. (NZ 2002)

RELATED TERMS: [coliforms](#)

infectious agent

Any organism, such as a pathogenic virus, parasite, or bacterium, that is capable of invading body tissues, multiplying, and causing disease. (EPA 2005b)

RELATED TERMS: [toxico-infectious pathogen](#), [toxinogenic pathogen](#)

infectious pathogen

One of three broad classes of foodborne pathogens—infectious, toxico-infectious or toxigenic—based on their modes of pathogenicity. Infectious pathogens typically have a three-step process by which they elicit a disease response: ingestion of viable cells, the attachment of these cells to specific locations along the gastro-intestinal tract (or some other mechanisms for avoiding being swept away due to peristalsis), and the invasion of either the epithelium (gastroenteritis) or the body proper (septicaemia). (Buchanan 2000)

infectiousness

- 1) The characteristic of a disease that concerns the relative ease with which it is transmitted to other hosts. A droplet spread disease, for instance, is more infectious than one spread by direct contact. The characteristics of the portals of exit and entry are thus also determinants of infectiousness, as are the agent characteristics of ability to survive away from the host and of infectivity. (MERREA 2005)
- 2) The state or quality of being infectious. (Stedman 2005)

RELATED TERMS: [infectivity](#), [infectibility](#)

infectivity

- 1) The proportion of persons exposed to a causative agent who become infected by an infectious disease. (CDC 2005)
- 2) The characteristic of a microorganism that allows it to infect and subsequently survive and multiply within a susceptible host. (Toma 1999)
- 3) The characteristic of a disease agent that embodies capability to enter, survive and multiply in the host; a measure of infectivity is the secondary attack rate; the proportion of exposures, in defined circumstances, that results in infection. (MERREA 2005)

RELATED TERMS: [infectiousness](#), [infectibility](#)

inoculum

- 1) Bacteria or fungi injected into compost to start biological action.
- 2) A medium containing organisms, usually bacteria or a virus, that is introduced into cultures or living organisms. (EPA 2005b)
- 3) The amount microorganisms introduced into a host. (MERREA 2005)

invasiveness

Degree to which an organism is able to spread through the body from a focus of infection. (CancerWeb 2005)

isolate

Isolate refers to a laboratory maintained stock or controlled propagation through host passages source of microorganisms. Isolates are used in the volunteer human feeding studies. In this context, it should not be implied that these isolates represent clonal populations of pathogens. There may be genetic variation within a stock batch and between generations. (EPA 2005f)

log inactivation

SEE: [log reduction](#)

log reduction

“Log” stands for logarithm, which is the exponent of 10. For example, \log^2 represents 10^2 or 10 x 10 or 100. Log reduction stands for a 10-fold or one decimal or 90% reduction in numbers of recoverable bacteria in a test food vehicle. Another way to look at it is: 1 log reduction would reduce the number of bacteria 90%. This means, for example, that 100 bacteria would be reduced to 10 or 10 reduced to 1. (FDA 2001)

RELATED TERMS: [log inactivation](#)

logarithmic growth curve (phase)

- 1) The steepest slope of the growth curve of a culture—the phase of vigorous growth during which cell number doubles every 20-30 minutes. (CancerWeb 2005)
- 2) Steep part of the growth curve of a bacterium or eukaryotic cell in culture during which cells divide rapidly. (Jones 2006)

RELATED TERMS: [exponential growth \(rate\)](#)

mechanical vector

A vector that conveys pathogens to a susceptible individual without essential biological development of the pathogens in the vector, as in the transfer of septic organisms on the feet or mouth parts of the housefly. (CancerWeb 2005, Stedman 2005)

RELATED TERMS: [vector](#)

mechanism of action

SEE: [mode of action](#)

mechanism of infection

The process by which a microorganism establishes itself in a host, including transmission, invasion, and multiplication. (ILSI 2000)

medium (*singular; plural, media*)

- 1) Material (e.g., air, water, soil, food, consumer products) surrounding or containing an agent. (IPCS 2004)
- 2) (**Media**) Specific environments—air, water, soil—that are the subject of regulatory concern and activities. (RAIS 2004)

RELATED TERMS: [environmental medium](#)

microbial growth

- 1) The amplification or multiplication of microorganisms such as bacteria, algae, diatoms, plankton, and fungi. (EPA 2005b)
- 2) Growth of microorganisms such as bacteria, algae, diatoms, plankton and fungi. (CRCWQT 2002)

microbial pesticides

Microorganisms that kill or inhibit pests, including insects or other microorganisms. Sometimes microorganisms get rid of pests simply by growing larger in numbers, using up the pests' food

supply, and invading the pests' environment. (EPA 2005e)

microorganism

- 1) Bacteria, yeasts, simple fungi, algae, protozoans, and a number of other organisms that are microscopic in size. Most are beneficial but some produce disease. Others are involved in composting and sewage treatment. (EPA 2005e)
- 2) Living organisms that can be seen individually only with the aid of a microscope. (CRCWQT 2002)
- 3) A microscopic life form that cannot be seen with the naked eye. Types of microorganisms include: bacteria, viruses, protozoa, fungi, yeasts, and some parasites and algae. (FDA 2001)

RELATED TERMS: [pathogen](#)

Prions are microscopic infectious agents and are sometimes grouped with microorganisms even though prions lack genetic material.

mobility

The ability of a chemical element or a pollutant to move into and through the environment (e.g., the mobilization of an element from a water column to sediment). (RAIS 2004)

mode of action

The term "mode of action" is defined as a sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation. Mode of action is contrasted with "mechanism of action," which implies a more detailed understanding and description of events, often at the molecular level, than is meant by mode of action. The toxicokinetic processes that lead to formation or distribution of the active agent to the target tissue are considered in estimating dose but are not part of the mode of action as the term is used here. There are many examples of possible modes of carcinogenic action, such as mutagenicity, mitogenesis, inhibition of cell death, cytotoxicity with reparative cell proliferation, and immune suppression. (EPA 2005a)

RELATED TERMS: [mechanism of action](#)**opportunistic pathogen**

A microorganism that does not ordinarily cause disease but that, under certain circumstances (e.g., impaired immune response resulting from other disease or drug treatment), elicits a pathogenic response. (ILSI 2000)

parasite

- 1) An organism which obtains food and shelter from another organism (for example, *Giardia*). (CancerWEB 2005)
- 2) A plant or animal that lives on or in another plant or animal, while making no beneficial contribution to that host. (FDA 2001)

RELATED TERMS: [protozoa](#)**pathogen**

- 1) Microorganisms (e.g., bacteria, viruses, or parasites) that can cause disease in humans,

- animals and plants. (EPA 2005b)
- 2) A bacterial organism typically found in the intestinal tracts of mammals, capable of producing disease. (EPA 2005e)
 - 3) A disease-causing microorganism; includes various types of bacteria, viruses, fungi and protozoa. (CRCWQT 2002)
 - 4) Any microorganism that is infectious or toxigenic and causes disease. Pathogens include parasites, viruses, and some fungi/yeast and bacteria. (FDA 2001)
 - 5) Organisms capable of causing disease. (MERREA 2005)
 - 6) A disease-causing agent, such as a certain bacterium, parasite, virus, or fungus. (USDA 2004)
 - 7) A pathogen is a virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, microorganisms). (OSTP 1986)

RELATED TERMS: [virulence-factor activity relationship](#)

Note that only one of the definitions of pathogen includes plasmids. That definition is from the 1986 Coordinated Framework for Regulation of Biotechnology. In 1986 the term virulence-factor activity relationship had not yet been proposed.

pathogen characterization

Evaluation of the characteristics of a pathogen that affect its ability to be transmitted to and cause disease in the host. (ILSI 2000)

pathogenesis

- 1) The origin and development of disease. (CancerWeb 2005)
- 2) The postulated mechanisms by which the etiologic agent produces disease. (MERREA 2005)
- 3) The pathologic, physiologic, or biochemical mechanism resulting in the development of a disease or morbid process. (Stedman 2005)

RELATED TERMS: [etiologic](#)

pathogenicity

- 1) The proportion of persons infected, after exposure to a causative agent, who then develops clinical disease. (CDC 2005)
- 2) The property of an organism that determines the extent to which overt disease is produced in an infected population, or the power of an organism to produce disease. Also used to describe comparable properties of toxic chemicals. Pathogenicity of infectious agents is measured by the ratio of the number of persons developing clinical illness to the number exposed to infection. (MERREA 2005)

plaque forming unit

ACRONYM: pfu/PFU

Refers to any entity which can give rise to a plaque. For example: if a phage stock solution has 1010 pfu/mL, it means that every mL of this stock has 1010 phage particles which can form plaques. This (pfu/mL) is the conventional way to refer the concentration of a phage preparation. (CancerWeb 2005)

practical quantitation limit

The lowest level of quantitation that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. (EPA 2004)

predictive microbiology

Analytical methods including mathematical modeling to estimate changes in bacterial numbers under different environmental or processing conditions, thus allowing assessment of the degree of contamination of a given medium. (ILSI 2000)

prion

A proteinaceous infectious agent that behaves as an inheritable trait, although it contains no nucleic acid. Examples are PrPSc, the agent of scrapie in sheep and bovine spongiform encephalopathy, and Psi, which confers an inherited state in yeast. (Jones 2006)

protozoa

- 1) One-celled animals that are larger and more complex than bacteria. May cause disease. (EPA 2005b)
- 2) Singular: protozoan. Single-celled microscopic animal. Plural protozoa. (CRCWQT 2002)

The use of the term “animals” in the first definition is phylogenetically incorrect.

quorum sensing

Quorum sensing is a form of communication between bacteria based on the use of signalling molecules that allows bacteria to coordinate their behaviour. The accumulation of signalling molecules in the environment enables a single cell to sense the number of bacteria (cell density).

Behavioural responses include adaptation to availability of nutrients, defence against other microorganisms that may compete for the same nutrients, and the avoidance of toxic compounds potentially dangerous for the bacteria. For example, it is very important for pathogenic bacteria during infection of a host (e.g., humans, other animals or plants) to coordinate their virulence in order to escape the immune response of the host in order to be able to establish a successful infection. (FAO/WHO 2003b)

RELATED TERMS: *contrast with* [minimum infective dose](#), [independent action](#)

resistance

- 1) In a body subject to infection, the sum total of body mechanisms that interpose barriers to the invasion or multiplication of infectious agents or to damage by their toxic products. (APHA 1995)
- 2) In a pathogen, the ability of a microorganism to adapt to and overcome the effects of antimicrobial drugs and/or host immune responses. (ILSI 2000)

spore

- 1) Highly resistant dehydrated form of reproductive cell produced under conditions of environmental stress. Usually have very resistant cell walls (integument) and low metabolic rate until activated. Bacterial spores may survive quite extraordinary

extremes of temperature, dehydration or chemical insult. Gives rise to a new individual without fusion with another cell. (CancerWeb 2005)

- 2) A thick-walled protective structure produced by certain bacteria and fungi to protect their cells. (FDA 2001)
- 3) Reproductive cells that are shed by an organism and divide to generate a new organism. In bacteria, they are produced by the special process of sporulation. In plants, they are haploid cells produced by meiosis. In fungi, they may be haploid cells produced by meiosis (sexual spores) or somatic cells that are cast off to make new individuals (asexual spores). (Jones 2006)
- 4) A specialized type of resting Gram positive bacterial cell, with a thick coat. Highly resistant to heat and chemicals. (Queensland Health 2005)
- 5) The asexual or sexual reproductive body of fungi or sporozoan protozoa. A cell of a plant lower in organization than the seed-bearing spermatophytic plants. A resistant form of certain species of bacteria. (Stedman 2005)

strain

- 1) A variant of a species of bacteria. Some may be pathogenic and some may be benign. For example, most *E. coli* are neutral or helpful to people, but *E. coli* O157:H7 is a strain of *E. coli* that is harmful to people. (FDA 2001)
- 2) A population of homogeneous organisms possessing a set of defined characteristics; in bacteriology, the set of descendants that retains the characteristics of the ancestor; members of a strain that subsequently differ from the original isolate are regarded as belonging either to a substrain of the original strain, or to a new strain. (Stedman 2005)

tolerance of pathogens to control

The ability of a microorganism to withstand specific environmental control measures (e.g., irradiation, temperature extremes, biocides, disinfection). (ILSI 2000)

toxico-infectious pathogen

One of three broad classes of foodborne pathogens—infectious, toxico-infectious or toxigenic—based on their modes of pathogenicity. Toxico-infectious agents follow a similar three-step process, except that instead of invading the epithelium or body, they remain in the gastro-intestinal tract, where they either produce or release toxins that affect sites of the epithelium and/or within the body. (Buchanan 2000)

RELATED TERMS: [infectious pathogen](#), [toxinogenic pathogen](#)

toxin

A poison that is produced by microorganisms, carried by fish, or released by plants. (FDA 2001)

RELATED TERMS: [toxicant](#)

toxinogenic pathogen

One of three broad classes of foodborne pathogens—infectious, toxico-infectious or toxigenic—based on their modes of pathogenicity. Toxinogenic bacteria are differentiated on the basis that they cause disease by producing toxins in foods prior to its ingestion. (Buchanan 2000)

RELATED TERMS: [infectious pathogen](#), [toxico-infectious pathogen](#)

transmissible

Capable of being transmitted (carried across) from one person to another, as a transmissible disease, an infectious or contagious disease. (CancerWeb 2005, Stedman 2005)

RELATED TERMS: [transmission of infection](#)

vegetative (bacterial) cell

Bacteria that are in the growth and reproductive phase, i.e., not spores. (Queensland Health 2005)

viable but not (non-) culturable (bacteria)

ACRONYM: VNBC, VNC

VNBC bacteria represent the part of the bacteria population, which is not able to grow in usual culture media and which cannot be resuscitated by traditional resuscitation techniques but which retain metabolic activity detected by various methods in the conditions tested. (Besnard et al. 2002)

virulence

- 1) The proportion of persons with clinical disease, who after becoming infected, become severely ill or die. (CDC 2004)
- 2) The degree of intensity of the disease produced by a microorganism as indicated by its ability to invade the tissues of a host and the ensuing severity of illness. (ILSI 2000)
- 3) The pathogenic or poisonous potential of bacteria, fungi, or other agents. (USDA 2004)

virulence factor

A general term for molecules that are produced by pathogens and allow pathogens to invade host organisms, cause disease, or evade immune responses (Jones 2006)

virulence-factor activity relationship

ACRONYM: VFAR

VFAR is a concept that was developed as a way to relate the architectural and biochemical components of a microorganism to its potential to cause human disease. (Jenkins et al. 2004)

virus

- 1) A non-cellular particle that consists minimally of protein or nucleic acid (DNA or RNA). In order to survive, it must replicate inside another cell, such as a bacterium or a plant and animal cell. (FDA 2001)
- 2) A large group of infectious agents, much smaller than bacteria, that is able to be viewed only through an electron microscope. They are not cells, but biologically active particles that vary in size from 0.01 to 0.1 microns. (CRCWQT 2002)

waterborne pathogen

A microorganism capable of causing disease that may be transmitted via water and acquired through ingestion, bathing, or by other means. (ILSI 2000)

5.4 HAZARD OCCURRENCE TERMS (PATHOGEN OCCURRENCE TERMS)

airborne transmission

- 1) The spread of infectious microorganisms through the air, usually over distances greater than one meter from the infected host. (Queensland Health 2005)

RELATED TERMS: [bioaerosol](#)

background levels

- 1) The concentration of a chemical already present in an environmental medium due to sources other than those under study. Two types of background levels may exist for chemical substances: (a) Naturally occurring levels of substances present in the environment, and (b) Anthropogenic concentrations of substances present in the environment due to human associated activities (e.g., automobiles, industries). (EPA 2004)
- 2) Two types of background levels may exist for chemical substances:
 - (a) Naturally occurring levels: ambient concentrations of substances present in the environment, without human influence.
 - (b) Anthropogenic levels: concentrations of substances present in the environment due to human-made, non-site sources (e.g., automobiles, industries). (EPA 2003)
- 3) The concentration of a substance in an environmental media (air, water, or soil) that occurs naturally or is not the result of human activities. In exposure assessment the concentration of a substance in a defined control area, during a fixed period of time before, during, or after a data-gathering operation. (EPA 2005b)
- 4) An average or expected amount of a substance or radioactive material in a specific environment, or typical amounts of substances that occur naturally in an environment. (ATSDR 2004)
- 5) In air pollution, the level of pollutants present in ambient air from natural sources. More generally, the level of pollution present in any environmental medium attributable to natural or ubiquitous sources. (RAIS 2004, SRA 2004)
- 6) The average amount of a substance present in the environment. Originally referring to naturally occurring phenomena. Used in toxic substance monitoring. (Stedman 2005)
- 2) The amount of an agent in a medium (e.g., water, soil) that is not attributed to the source(s) under investigation in an exposure assessment. Background level(s) can be naturally occurring or the result of human activities. (Note: Natural background is the concentration of an agent in a medium that occurs naturally or is not the result of human activities.) (IPCS 2004)

Note that in some cases the definition is limited to natural sources and in other cases natural and anthropogenic sources are added together.

background source

Any source from which pollutants are released and contribute to the background level of a pollutant, such as volcano eruptions, windblown dust, or manmade source upwind of the study area. (EPA 2004)

biological monitoring

- 1) The measurement of chemicals in biological media (e.g., blood, urine, exhaled breath) to determine whether chemical exposure in humans, animals, or plants has occurred. (EPA 2004)
- 2) Measuring hazardous substances in biologic materials (such as blood, hair, urine, or breath) to determine whether exposure has occurred. A blood test for lead is an example of biologic monitoring. (ATSDR 2004)
- 3) Biomonitoring: 1. The use of living organisms to test the suitability of effluents for discharge into receiving waters and to test the quality of such waters downstream from the discharge. 2. Analysis of blood, urine, tissues, etc. to measure chemical exposure in humans. (EPA 2005b)

biosensor

Analytical device comprising a biological recognition element (e.g. enzyme, receptor, DNA, antibody, or microorganism) in intimate contact with an electrochemical, optical, thermal, or acoustic signal transducer that together permit analyses of chemical properties or quantities. Shows potential development in some areas, including environmental monitoring. (EPA 2005b)

composite sample

- 1) A series of water samples taken over a given period of time and weighted by flow rate. (EPA 2005b)
- 2) A sample of water, soil or other medium which is made by combining samples from two or more locations. (NYDOH1999)

Note: composite samples may be used in sampling for microorganisms in the environment especially if there is a desire to provide estimates of microbial concentrations over some discrete period of time.

concentration

- 1) The relative amount of a substance mixed with another substance. An example is five ppm of carbon monoxide in air or 1 mg/l of iron in water. (EPA 2005b, EPA 2005e)
- 2) The amount of a substance present in a certain amount of soil, water, air, food, blood, hair, urine, breath, or any other media. (ATSDR 2004)
- 3) Amount of a material or agent dissolved or contained in unit quantity in a given medium or system. (IPCS/OECD 2004)

cross-contamination

- 1) The movement of underground contaminants from one level or area to another due to invasive subsurface activities. (EPA 2005b)
- 2) Direct or indirect transfer of a pathogen from one medium (e.g., food or water) to another. (ILSI 2000)

detection limit

- 1) The lowest concentration of a chemical that can reliably with analytical methods be distinguished from a zero concentration. (EPA 2004)
- 2) The lowest concentration of a chemical that can reliably be distinguished from a zero

concentration. (EPA 2005b, ATSDR 2004)

environmental fate model

In the context of exposure assessment, any mathematical abstraction of a physical system used to predict the concentration of specific chemicals as a function of space and time subject to transport, intermedia transfer, storage, and degradation in the environment. (EPA 1992)

environmental medium

Any one of the major categories of material found in the physical environment (e.g., surface water, ground water, soil, or air), and through which chemicals or pollutants can move. (EPA 2004)

RELATED TERMS: [medium](#)

fate

Pattern of distribution of an agent, its derivatives or metabolites in an organism, system, compartment or (sub) population of concern as a result of transport, partitioning, transformation or degradation. (IPCS/OECD 2004)

fate and transport

A description of how a chemical is carried through and changes in the environment. (EPA 2004)

fate and transport analysis

The general process used to assess and predict the movement and behavior of chemicals in the environment. (EPA 2004)

grab sample

- 1) A single sample collected at a particular time and place that represents the composition of the water, air, or soil only at that time and place. (EPA 2004)
- 2) A single sample of soil or of water taken without regard to time or flow. (EPA 2005e)

interferents

Interferents are anything that interfere with obtaining an accurate result for an assay (e.g., a PCR assay). Interferents include reaction inhibitors, but are not limited to substances that directly interact with enzymes. The source of interferents is the environmental or clinical sample matrix. (EPA 2005f)

limit of detection**ACRONYM:** LOD

- 1) The minimum concentration of a substance being analyzed test that has a 99 percent probability of being identified. (EPA 2005b)
- 2) The LOD is the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity, or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The LOD is considered synonymous with the limit of quantitation/quantification.

(FAO/WHO 1997)

limit of quantification**ACRONYM:** LOQ

- 1) LOQ is the point at which “measurements become quantitatively meaningful” (Taylor 1987). It is the lowest pesticide residue that can be accurately quantitated in a reproducible fashion. The LOQ can be defined in a number of ways, such as the background response plus ten times the standard deviation of the lowest measurable concentration, ten times the signal-to-noise ratio of the baseline noise, ten times the standard deviation of the lowest measurable concentration, etc. In practice, the LOQ is the lowest fortification level that shows adequate recovery during the method validation process. (EPA 1998b)
- 2) The smallest amount of the pesticide that can be quantified by the analytical method. (OECD 1997)

lower detection limit

The smallest signal above background noise an instrument can reliably detect. (EPA 2005b)

monitoring

- 1) Periodic or continuous physical surveillance or testing to determine pollutant levels in various environmental media or in humans, plants, and animals. (EPA 2004)
- 2) Periodic or continuous surveillance or testing to determine the level of compliance with statutory requirements and/or pollutant levels in various media or in humans, plants, and animals. (EPA 2005b, RAIS 2004)
- 3) The act of conducting a planned series of observations or measurements of operational and/or critical limits to assess whether a control point is under control. (KIWA 2004)

most probable number**ACRONYM:** MPN

An estimate of microbial density per unit volume of water sample, based on probability theory. (EPA 2005b)

natural source

Non-manmade emission sources, including biological (biogenic sources such as plants) and geological sources (such as volcanoes), and windblown dust. (EPA 2004)

RELATED TERMS: [anthropogenic](#)

pathogen occurrence

A description of the frequency of appearance of a pathogen in a medium, including identification of peaks, average levels, frequency of detection, distribution, seasonal variation, and association with other temporal or spatial changes. (ILSI 2000)

persistence

- 1) Refers to the length of time a compound stays in the environment, once introduced. A

compound may persist for very short amounts of time (e.g., fractions of a second) or for long periods of time (e.g., hundreds of years). (EPA 2004)

- 2) Refers to the length of time a compound stays in the environment, once introduced. A compound may persist for less than a second or indefinitely. (EPA 2005b)
- 3) The ability of a pathogen to remain in a host or in the environment for extended periods of time. (ILSI 2000)
- 4) The quality of remaining for a long period of time (such as in the environment or the body). Persistent chemicals (such as DDT and PCBs) are not easily broken down. (NYDOH 1999)

precision

- 1) A measure of the reproducibility of a measured value under a given set of circumstances. (EPA 1997a, EPA 2004)
- 2) A measure of the reproducibility of the predictions of a model or repeated measurements, usually in terms of the standard deviation or other measures of variation among such predictions or measurements. (FAO/WHO 2003b)
- 3) The quality of being sharply defined or stated. One measure of precision is the number of distinguishable alternatives from which a measurement was selected, sometimes indicated by the number of significant digits in the measurement. Another measure of precision is the standard error of measurement, the standard deviation of a series of replicate determinations of the same quantity. See also measurement, problems with terminology. *Statistics*: Precision is defined as the inverse of the variance of a measurement or estimate. (Last 1983)
- 4) The degree to which a measurement (e.g., the mean estimate of a treatment effect) is derived from a set of observations having small variation (i.e., close in magnitude to each other). A narrow confidence interval indicates a more precise estimate of effect than a wide confidence interval. A precise estimate is not necessarily an accurate one. (NLM/NICHSR 2004)
- 5) A measure of how consistently the result is determined by repeated determinations without reference to any “true” value. (RAIS 2004, SRA 2004)
- 6) Precision is a measure of how close an estimator is expected to be to the true value of a parameter. Precision is usually expressed in terms of imprecision and related to the standard error of the estimator. Less precision is reflected by a larger standard error. (STEPS 1997)

RELATED TERMS: [parameter](#)

presumptive count

An estimate of the number of bacteria of a specific group in a sample, as revealed by an initial screening test. Requires further testing to be confirmed. (NZ 2002)

representativeness

- 1) The degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences. (EPA 1997a)
- 2) The property of a sample (set of observations) that they are characteristic of the system from which they are a sample or which they are intended to represent, and thus

appropriate to use as the basis for making inferences. A representative sample is one that is free of unacceptably large bias with respect to a particular data quality objective. (FAO/WHO 2003b)

representative sample

A portion of material or water that is as nearly identical in content and consistency as possible to that in the larger body of material or water being sampled. (EPA 2005b)

reproducibility

The degree of variation obtained when the same measurement is made with similar instruments and many operators. (RAIS 2004, SRA 2004)

reservoir

- 1) The habitat in which an infectious agent normally lives, grows and multiplies; reservoirs include human reservoirs, animals reservoirs, and environmental reservoirs. (CDC 2005)
- 2) Any natural or artificial holding area used to store, regulate, or control water. (CRCWQT 2002)
- 3) Any biological or environmental milieu that supports the maintenance and/or growth of pathogenic organisms. Such reservoirs can be the sources of both epidemic and endemic infections. (ILSI 2000)

sample

- 1) A portion or piece of a whole. A selected subset of a population or subset of whatever is being studied. For example, in a study of people the sample is a number of people chosen from a larger population. An environmental sample (for example, a small amount of soil or water) might be collected to measure contamination in the environment at a specific location. (ATSDR 2004)
- 2) A specimen of a whole entity small enough to involve no threat or damage to the whole; an aliquot. A selected subset of a population; a sample may be random or nonrandom (haphazard); representative or nonrepresentative. (CancerWeb 2005)
- 3) A selected subset of a population. A sample may be random or non-random and it may be representative or non-representative. (CDC 2005)
- 4) A sub-group of the population of interest that has been selected for study. (ESOMAR 2001)
- 5) A specimen that is taken from food and tested for the purpose of identifying a foodborne pathogen or various kinds of chemical contaminants in food. (FDA 2001)
- 6) Material collected from a source other than an animal or man for laboratory analysis (such as water sample or soil sample). (MERREA 2005)
- 7) The set of observational units (wafers, people, etc) whose properties our study is to observe. When we select a sample by scientific randomization, we are more easily able to generalize our conclusions to the population of interest. As opposed to population. For a given characteristic, the collection of measurements that are actually observed. (NIST/SEMATECH 2005b)
- 8) A sample is a group of units selected from a larger group (the population). By studying the sample it is hoped to draw valid conclusions about the larger group. A sample is

generally selected for study because the population is too large to study in its entirety. The sample should be representative of the general population. This is often best achieved by random sampling. Also, before collecting the sample, it is important that the researcher carefully and completely defines the population, including a description of the members to be included. (STEPS 1997)

RELATED TERMS: *contrast with* [population](#)

sampling distribution

- 1) A probability distribution for a statistic. (FAO/WHO 2003b)
- 2) The distribution of a summary quantity or statistic. (NIST/SEMATECH 2005b)
- 3) The sampling distribution describes probabilities associated with a statistic when a random sample is drawn from a population. The sampling distribution is the probability distribution or probability density function of the statistic. Derivation of the sampling distribution is the first step in calculating a confidence interval or carrying out a hypothesis test for a parameter. (STEPS 1997)

RELATED TERMS: [distribution](#), [population](#), [sample](#)

seasonality

Change in physiological status or in disease occurrence that conforms to a regular seasonal pattern. (CDC 2005)

systematic error

A reproducible inaccuracy introduced by faulty equipment, calibration, or technique. (RAIS 2004, SRA 2004)

RELATED TERMS: [bias](#)

temporal variability

The difference in contaminant concentrations observed in samples taken at different times. (EPA 2004)

time-averaged exposure

The time-integrated exposure divided by the exposure duration. An example is the daily average exposure of an individual to carbon monoxide. (Also called time-weighted average exposure.) (IPCS 2004)

time-integrated exposure

The integral of instantaneous exposures over the exposure duration. An example is the area under a daily time profile of personal air monitor readings, with units of concentration multiplied by time. (IPCS 2004)

time-integrated sample

Samples are collected over a period of time. Only the total pollutant collected is measured, and so only the average concentration during the sampling period can be determined. (EPA 2004)

time-trend study

Samples spaced in time to capture systematic temporal trends (e.g., a facility might change its production methods or products over time). (EPA 2004)

5.5 EXPOSURE TERMS

absorbed dose

- 1) The amount of a substance penetrating across an absorption barrier (the exchange boundaries) of an organism, via either physical or biological processes. Sometimes called internal dose. (EPA 1992)
- 2) The amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. (EPA 2005b)
- 3) The amount of a substance absorbed into the body, usually per unit of time. The most common unit of dose is mg per kg body weight per day (mg/kg-day). (RAIS 2004, SRA 2004)

RELATED TERMS: [dose](#)

absorption barrier

Any exposure surface that may retard the rate of penetration of an agent into a target. Examples of absorption barriers are the skin, respiratory tract lining, and gastrointestinal tract wall (see also *Exposure surface*). (IPCS 2004)

activity pattern data

Information on human activities used in exposure assessments. These may include a description of the activity, frequency of activity, duration spent performing the activity, and the microenvironment in which the activity occurs. (IPCS 2004)

acute exposure

- 1) Exposure by the oral, dermal, or inhalation route for 24 hours or less. (EPA 2003)
- 2) One dose (or exposure) or multiple doses (or exposures) occurring within a short time relative to the life of a person or other organism (e.g., approximately 24 hours or less for humans). (EPA 2004)
- 3) A single exposure to a toxic substance that results in severe biological harm or death. Acute exposures are usually characterized as lasting no longer than a day, as compared to longer, continuing exposure over a period of time. (EPA 2005b, RAIS 2004)
- 4) Contact with a substance that occurs once or for only a short time (up to 14 days). (ATSDR 2004)
- 5) A contact between an agent and a target occurring over a short time, generally less than a day. (Other terms, such as “short-term exposure” and “single dose,” are also used.) (IPCS 2004)

RELATED TERMS: *contrast with* [chronic exposure](#)

acute exposure limits

A variety of short-term exposure limits to hazardous substances, designed to be protective of human health. Published by different organizations, each limit has a different purpose and definition. (EPA 2004)

acute toxicity

- 1) Any poisonous effect produced within a short period of time following an exposure,

usually 24 to 96 hours. (EPA 2003)

- 2) The ability of a substance to cause severe biological harm or death soon after a single exposure or dose. Also, any poisonous effect resulting from a single short-term exposure to a toxic substance. (EPA 2005b)
- 3) Adverse effects that result from a single dose or single exposure of a chemical; any poisonous effect produced within a short period of time, usually less than 96 hours. This term normally is used to describe effects in experimental animals. (EPA 2005e)
- 4) Adverse effects occurring within a short time (usually up to 14 days) after administration of a single dose of test substance, or after multiple doses administered within 24 hours. (ILSI 2001)

RELATED TERMS: *contrast with* [chronic toxicity](#)

adjusted exposure concentration

An estimate of exposure concentration that has been refined, usually by application of an exposure model, to better understand how people in a particular location interact with contaminated media. (EPA 2004)

RELATED TERMS: [refined exposure concentration](#)

administered dose

- 1) The amount of a substance received by a test subject (human or animal) in determining dose-response relationships, especially through ingestion or inhalation. (EPA 2004)
- 2) In exposure assessment, the amount of a substance given to a test subject (human or animal) to determine dose-response relationships. Since exposure to chemicals is usually inadvertent, this quantity is often called potential dose. (EPA 2005b)

The method of administration (e.g., dermal, injection, inhalation, ingestion) is also an important aspect of administered dose.

adsorption

Removal of a pollutant from air or water by collecting the pollutant on the surface of a solid material; e.g., an advanced method of treating waste in which activated carbon removes organic matter from waste-water (EPA 2005b)

Note that adsorption is different from absorption. Adsorption often means the physical attachment or adhesion of one substance to the surface of another substance. Microbial adsorption to particulate materials in water may be observed and this can affect the fate and transport of the microbial entities.

aerosol

- 1) A suspension of liquid or solid particles in air. (EPA 2003)
- 2) Small droplets or particles suspended in the atmosphere, typically containing sulfur. They are usually emitted naturally (e.g. in volcanic eruptions) and as the result of anthropogenic (human) activities such as burning fossil fuels. (EPA 2005b)
- 3) A fine mist or spray that contains minute particles and may contain microorganisms. (Queensland Health 2005)
- 4) System in which the dispersion medium is a gas and the dispersed phase (composed of solid particles or liquid droplet) does not settle out under the influence of gravity. (SRA

2004)

RELATED TERMS: [bioaerosol](#)

aggregate exposure

- 1) The sum of exposures to pesticide chemical residues with a common mechanism of toxicity from multiple sources and multiple routes of exposure. (EPA 1997a)
- 2) The combined exposure of an individual (or defined population) to a specific agent or stressor via relevant routes, pathways, and sources. (EPA 2004)
- 3) The sum total of all exposure to pesticides through inhalation, or dermal, oral, or optic contact. (EPA 2005e)

ambient level

The level (of pollutant) in the general environment as characterized by an average over a suitably long time and large volume. (RAIS 2004, SRA 2004)

ambient measurement

A measurement of the concentration of a substance or pollutant within the immediate environs of an organism; taken to relate it to the amount of possible exposure. (EPA 2005b)

applied dose

The amount of a substance in contact with an absorption boundary of an organism (e.g., skin, lung, gastrointestinal tract) and is available for absorption. (EPA 2004)

RELATED TERMS: [dose](#)

average daily dose

ACRONYM: ADD

- 1) Dose that is averaged over a specified time period taking into account the frequency, duration, and intensity of exposure during that time period. ADDs are usually expressed in units of mg/kg/day. (EPA 1998a)
- 2) Dose rate averaged over a pathway-specific period of exposure expressed as a daily dose on a per-unit-body-weight basis. The ADD is usually expressed in terms of mg/kg-day or other mass-time units. (EPA 2003)

averaging time

The time period over which something is averaged (e.g., exposure, measured concentration). (EPA 2004)

bioaccumulation

- 1) The net accumulation of a substance by an organism as a result of uptake from and or all routes of exposure (e.g., ingestion of food, intake of drinking water, direct contact, or inhalation). (EPA 2004)
- 2) A process where chemicals are retained in fatty body tissue and increase in concentration over time. (EPA 2005e)
- 3) The process whereby certain toxic substances collect in living tissues, thus posing a substantial hazard to human health or the environment. (RAIS 2004, SRA 2004)

RELATED TERMS: [bioconcentration](#), [biomagnification](#)

bioaccumulation factor

ACRONYM: BAF

The concentration of a substance in tissue of an organism divided by its concentration in an environmental medium in situations where the organism and its food are exposed (i.e., accounting for food chain exposure as well as direct chemical uptake). (EPA 1999a)

bioaerosol

- 1) Organisms or biological agents that can be dispersed through the air and that have the potential to affect human health (NSWEPA 2004)

RELATED TERMS: [aerosol](#), [airborne transmission](#)

bioconcentration

- 1) The net accumulation of a substance by an organism as a result of uptake directly from an environmental medium (e.g., net accumulation by an aquatic organism as a result of uptake directly from ambient water, through gill membranes or other external body surfaces). (EPA 2004)
- 2) The tendency of a chemical to accumulate in a living organism to levels in excess of the concentration in its surrounding environment. (AIHA 2000)

bioconcentration factor

ACRONYM: BCF

The concentration of a substance in tissue of an organism divided by the concentration in an environmental medium (e.g., the concentration of a substance in an aquatic organism divided by the concentration in the ambient water, in situations where the organism is exposed through the water only). (EPA 2004)

biologically effective dose

The amount of chemical that reaches the cells or target site where an adverse effect may occur. (EPA 2004)

biomagnification (biological magnification)

- 1) The process whereby certain substances, such as pesticides or heavy metals, transfer up the food chain and increase in concentration. For example, a biomagnifying chemical deposited in rivers or lakes absorbs to algae, which are ingested by aquatic organisms, such as small fish, which are in turn eaten by larger fish, eating birds, terrestrial wildlife, or humans. The chemical tends to accumulate to higher concentration levels with each successive food chain level. (EPA 2004)
- 2) Biomagnification is the increase of tissue accumulation in species higher in the natural food chain as contaminated food species are eaten. (EPA 2005e)
- 3) The concentration of certain substances up a food chain. A very important mechanism in concentrating pesticides and heavy metals in organisms such as fish. (RAIS 2004, SRA 2004)

chronic exposure

- 1) Repeated exposure by the oral, dermal, or inhalation route for more than approximately 10% of the life span in humans (more than approximately 90 days to 2 years in typically used laboratory animal species). (EPA 2003)
- 2) Continuous exposure, or multiple exposures, occurring over an extended period of time or a significant fraction of the animal's or the individual's lifetime. (EPA 2004)
- 3) Multiple exposures occurring over an extended period of time or over a significant fraction of an animal's or human's lifetime (usually seven years to a lifetime). (EPA 2005b)
- 4) Contact with a substance that occurs over a long time (more than one year). (ATSDR 2004)
- 5) Multiple exposures occurring over an extended period of time, or a significant fraction of the animal's or the individual's lifetime. (RAIS 2004)
- 6) A continuous or intermittent long-term contact between an agent and a target. (Other terms, such as "long-term exposure," are also used.) (IPCS 2004)

RELATED TERMS: *contrast with* [acute exposure](#)

cocktail effect

A term commonly used to describe the possible effect on people of being exposed to a mixture of chemical residues, for example of different pesticides. (FSA 2005)

consumption rate

The average quantity of an item consumed or expended during a given time interval, expressed in quantities by the most appropriate unit of measurement per applicable stated basis. (EPA 2004)

contact

- 1) Exposure to a source of an infection, or a person so exposed. (CDC 2005)
- 2) A person or animal that has been in such association with an infected person or animal or a contaminated environment as to have had opportunity to acquire the infection. (MERREA 2005)
- 3) The touching or apposition of two bodies. A person who has been exposed to a contagious disease. (Stedman 2005)

RELATED TERMS: [direct contact](#), [indirect contact](#), [primary contact](#)

contact volume

A volume containing the mass of agent that contacts the exposure surface. (IPCS 2004)

cumulative exposure

The sum of exposures of an organism to a pollutant over a period of time. (EPA 2005b)

direct contact

A mode of transmission of infection between an infected host and susceptible host. Direct contact occurs when skin or mucous surfaces touch, as in shaking hands, kissing, and sexual intercourse. (MERREA 2005)

RELATED TERMS: [contact](#), [primary contact](#); *contrast with* [indirect contact](#)

estimated exposure dose

ACRONYM: EED

The measured or calculated dose to which humans are likely to be exposed considering all sources and routes of exposure. (EPA 2003)

exposed

- 1) A group whose members have been exposed to a supposed cause of disease or health state of interest, or possess a characteristic that is a determinant of the health outcome of interest. (CDC 2005)
- 2) In epidemiology, the exposed group (or simply, the exposed) is often used to connote a group whose members have been exposed to a supposed cause of a disease or health state of interest, or possess a characteristic that is a determinant of the health outcome of interest. (Last 1983)
- 3) In epidemiology, the exposed group (or simply, the exposed) is often used to connote a group whose members have been exposed to a supposed cause of a disease or health state of interest or possess a characteristic that is a determinant of the health outcome of interest. (MERREA 2005)

exposure

- 1) The contact or co-occurrence of a stressor with a receptor. (EPA 1998a)
- 2) Contact made between a chemical, physical, or biological agent and the outer boundary of an organism. Exposure is quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut). (EPA 2003)
- 3) Contact made between a chemical, physical, or biological agent and the outer boundary of an organism. (EPA 2004)
- 4) The amount of radiation or pollutant present in a given environment that represents a potential health threat to living organisms. (EPA 2005b)
- 5) Radiation or pollutants that come into contact with the body and present a potential health threat. The most common routes of exposure are through the skin, mouth, or by inhalation. (EPA 2005e)
- 6) Contact with a substance by swallowing, breathing, or touching the skin or eyes. Exposure may be short-term (acute exposure), of intermediate duration, or long-term (chronic exposure). (ATSDR 2004)
- 7) Contact of a chemical, physical or biological agent with the outer boundary of an organism, for example inhalation, ingestion, or contact with the skin. (CRCWQT 2002)
- 8) The level of a substance, for example a chemical, that a person or animal may be subjected to intentionally or non-intentionally. People can be exposed to substances through food, water and their environment. (FSA 2005)
- 9) Concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration. (IPCS/OECD 2004)
- 10) Concentration or amount of an infectious micro-organism that reaches the target population, or organism usually expressed in numerical terms of substance, concentration, duration, and frequency. (KIWA 2004)

- 11) Contact with a substance by swallowing, breathing, direct contact (such as through the skin, eyes or mucous membranes) or intravenous injection. Exposure may be either short term (acute) or long term (chronic). (NYS 1998)
- 12) Any characteristic or event that might cause or prevent disease. (NZ 2002)
- 13) The time integral of the concentration of a toxicant that is in the immediate vicinity of various ports of entry (such as lung, GI tract, and skin). (RAIS 2004, SRA 2004)
- 14) Contact between an agent and a target. Contact takes place at an exposure surface over an exposure period. (IPCS 2004)

Definition #10 considers exposure in both harmful and beneficial contexts, whereas all the other definitions either state or imply that exposure refers to harmful agents only. Definition #7 specifically includes duration of the contact. Although not specifically stated in most of the other definitions, the importance of duration can be implied. In several of the definitions the concentration or dose of the hazard is included.

exposure analysis

The process of characterizing the source and temporal nature of human exposure to a pathogenic microorganism. (ILSI 2000)

RELATED TERMS: [exposure assessment](#)

exposure assessment

- 1) The determination or estimation (qualitative or quantitative) of the magnitude, frequency, or duration, and route or exposure. (EPA 1997a)
- 2) An identification and evaluation of a population exposed to a toxic agent, describing its composition and size, as well as the type, magnitude, frequency, route, and duration of exposure. (EPA 2003, 2004)
- 3) Identifying the pathways by which toxicants may reach individuals, estimating how much of a chemical an individual is likely to be exposed to, and estimating the number likely to be exposed. (EPA 2005b)
- 4) The process of finding out how people come into contact with a hazardous substance, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with. (ATSDR 2004)
- 5) The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant. (CAC 1999, CAC 2003, FAO/WHO 2003b)
- 6) A component of a risk assessment that characterizes the source and magnitude of human exposure to the hazard. (FDA 2002)
- 7) The process of determining or estimating the magnitude, frequency or duration of exposure to a substance such as a chemical. This may involve taking measurements from many sources to produce an aggregate (combined) assessment. (FSA 2005)
- 8) Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives). Exposure Assessment is the third step in the process of Risk Assessment. (IPCS/OECD 2004)
- 9) Qualitative and/or quantitative evaluation of the likely intake of microbial hazard via all relevant sources or a specific source. (KIWA 2004)
- 10) The process of measuring or estimating the intensity, frequency, and duration of human

exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment. (MERREA 2005, RAIS 2004, SRA 2004)

- 11) The process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposure that might arise from the release of new chemicals into the environment. In its most complete form, it describes the magnitude, duration, schedule, and route of exposures; the size, nature, and classes of the human populations exposed; and the uncertainties in all estimates. Exposure assessment is often used to identify feasible prospective control options and to predict the effects of available control technologies on exposure. (NRC 1983)
- 12) A process that estimates the amount of a chemical that enters or comes into contact with people. An exposure assessment also describes the length of time and the nature and size of a population exposed to a chemical. (NYDOH 1999)
- 13) Exposure assessment is the determination of the amount, duration, and frequency of an actual or hypothetical exposure of people, organisms, or the environment to a substance or an activity that can affect health, the environment, or the ecosystem. Exposure assessments specify the population that might be exposed, identifies the routes through which exposure can occur, and estimates the magnitude, duration, and timing of the doses that people might receive as a result of their exposure. (NYS 1998)
- 14) The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the assessment. (IPCS 2004)

RELATED TERMS: [exposure analysis](#)

exposure concentration

- 1) The concentration of a chemical in its transport or carrier medium (i.e., an environmental medium or contaminated food) at the point of contact. (EPA 1997a, EPA 2004)
- 2) The concentration of a chemical or other pollutant representing a health threat in a given environment. (EPA 2005b)
- 3) The exposure mass divided by the contact volume or the exposure mass divided by the mass of contact volume, depending on the medium. (IPCS 2004)

exposure duration

- 1) The total time an individual is exposed to the chemical being evaluated or the length of time over which contact with the contaminant lasts. (EPA 2004)
- 2) Toxicologically, there are three categories describing duration of exposure: acute (one-time), subchronic (repeated, for a fraction of a lifetime), and chronic (repeated, for nearly a lifetime). (REAP 1995)
- 3) The length of time over which continuous or intermittent contacts occur between an agent and a target. For example, if an individual is in contact with an agent for 10 min per day for 300 days over a 1-year time period, the exposure duration is 1 year. (IPCS 2004)

exposure event

The occurrence of continuous contact between an agent and a target. (IPCS 2004)

exposure factor

Any of a variety of factors that relate to how an organism interacts with or is otherwise exposed to environmental pollutants (e.g., ingestion rate of contaminated fish). Such factors are used in the calculation of exposure to toxic chemicals. (EPA 2004)

exposure investigation

In public health assessment, the collection and analysis of site-specific information and biologic tests (when appropriate) to determine whether people have been exposed to hazardous substances. (EPA 2004)

exposure loading

The exposure mass divided by the exposure surface area. For example, a dermal exposure measurement based on a skin wipe sample, expressed as a mass of residue per skin surface area, is an exposure loading. (IPCS 2004)

exposure mass

The amount of agent present in the contact volume. For example, the total mass of residue collected with a skin wipe sample over the entire exposure surface is an exposure mass. (IPCS 2004)

exposure model

- 1) A conceptual or mathematical representation of the exposure process. (IPCS 2004)

exposure modeling

The mathematical equations simulating how people interact with chemicals in their environment. (EPA 2004)

exposure pathway

- 1) The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway includes a source and release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also is included. (EPA 2004)
- 2) The path from sources of pollutants via soil, water, or food to man and other species or settings. (EPA 2005b)
- 3) pathway of exposure - The physical course a pesticide takes from the source to the organism exposed (e.g., through food or drinking water consumption or residential pesticide uses). (EPA 2005e)
- 4) The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an environmental media and transport mechanism (such as movement through groundwater); a point of exposure (such as a private well); a route of exposure (eating,

drinking, breathing, or touching), and a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway. (ATSDR 2004)

- 5) The process by which an individual is exposed to contaminants or disease organisms that originate from a specified source. An exposure pathway consists of the following five elements: source of contamination, environmental media and transport mechanisms, point of exposure, route of exposure, and receptor population. (NYS 1998)
- 6) The course an agent takes from the source to the target. (IPCS 2004)

exposure period

The time of continuous contact between an agent and a target. (IPCS 2004)

exposure point

- 1) An exact location of potential contact between a person and a chemical within an exposure medium. (EPA 1999b)
- 2) Location of potential contact between an organism and a chemical or physical agent. (AIHA 2000)

exposure profile

- 1) A summary of the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model. (EPA 1998a)
- 2) The exposure profile (ecological) identifies the receptors and describes the exposure pathways and intensity and spatial and temporal extent of exposure. It also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur. The profile may be a written document or a module of a larger process model. (EPA 2004)
- 3) A qualitative and/or quantitative evaluation of the magnitude, frequency, and pattern of exposure to a pathogen, developed during the analysis phase of microbial risk assessment, including a description of the assumptions and uncertainties inherent in such an evaluation. (ILSI 2000)

exposure-response

Exposure-response has been used by EPA when referring to hazards that are not necessarily pathogens. For example, exposure to indicator bacteria may be correlated with a response (gastrointestinal illness), but the indicator is not the cause of the response. Referring to a “dose of indicators” is misleading because it implies the indicator is the causative agent of the health endpoint.

SEE: [dose-response](#)

exposure-response relationship

The relationship between exposure level and the incidence of adverse effects. (EPA 2005b)

exposure route

- 1) The way a chemical enters an organism after contact (e.g., by ingestion, inhalation,

dermal absorption). (EPA 1997a, EPA 2004, EPA 2005b)

- 2) The way in which an agent enters a target after contact (e.g., by ingestion, inhalation, or dermal absorption). (IPCS 2004)

RELATED TERMS: [route of exposure](#)

exposure scenario

- 1) A set of conditions or assumptions about sources, exposure pathways, concentrations of toxic chemicals, and populations (numbers, characteristics and habits) which aid the investigator in evaluating and quantifying exposure in a given situation. (EPA 2004)
- 2) A set of conditions or assumptions about sources, exposure pathways, amount or concentrations of agent(s) involved, and exposed organism, system or (sub) population (i.e., numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation. (IPCS/OECD 2004)
- 3) A set of assumptions concerning how an exposure may take place, including exposure setting, stressor characteristics, and activities that may lead to exposure. (EPA 1998a)
- 4) A combination of facts, assumptions, and inferences that define a discrete situation where potential exposures may occur. These may include the source, the exposed population, the time frame of exposure, microenvironment(s), and activities. Scenarios are often created to aid exposure assessors in estimating exposure. (IPCS 2004)

exposure surface

A surface on a target where an agent is present. Examples of outer exposure surfaces include the exterior of an eyeball, the skin surface, and a conceptual surface over the nose and open mouth. Examples of inner exposure surfaces include the gastrointestinal tract, the respiratory tract, and the urinary tract lining. As an exposure surface gets smaller, the limit is an exposure point. (IPCS 2004)

exposure unit

In geographical information system applications, the geographical area in which a receptor moves and contacts the contaminated medium during the period of exposure. (EPA 2004)

high-end exposure estimate

A plausible estimate of individual exposure or dose for those persons at the upper end of an exposure or dose distribution, conceptually above the 90th percentile, but not higher than the individual in the population who has the highest exposure or dose. (EPA 2004)

incidental ingestion

Unintentional intake of small amounts of agents, particularly associated with children's from hand-to-mouth activity. (REAP 1995)

indirect contact

A mode of transmission of infection involving fomites or vectors. Vectors may be mechanical (e.g., filth, flies) or biological (the disease agent undergoes part of its life cycle in the vector species). (MERREA 2005)

RELATED TERMS: [contact](#); *contrast with* [direct contact](#)

indirect exposure

Often defined as an exposure involving multimedia transport of agents from source to exposed individual. Examples include exposures to chemicals deposited onto soils from the air, chemicals released into the ground water beneath a hazardous waste site, or consumption of fruits or vegetables with pesticide residues. (REAP 1995)

ingestion

- 1) Swallowing (such as eating or drinking). (EPA 2004)
- 2) The act of swallowing something through eating, drinking, or mouthing objects. A hazardous substance can enter the body this way. (ATSDR 2004)

RELATED TERMS: [route of exposure](#)

ingestion exposure

Exposure to a chemical by swallowing it (such as eating or drinking). (EPA 2004)

RELATED TERMS: [route of exposure](#)

inhalation

- 1) Breathing. (EPA 2004)
- 2) The act of breathing. A hazardous substance can enter the body this way. (ATSDR 2004)

RELATED TERMS: [route of exposure](#)

inhalation exposure

Exposure to a chemical by breathing it in. (EPA 2004)

RELATED TERMS: [route of exposure](#)

inhalation unit risk

ACRONYM: IUR

The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/m³ in air. The interpretation of unit risk would be as follows: if unit risk = 2×10^{-6} µg/m³, 2 excess tumors may develop per 1,000,000 people if exposed daily for a lifetime to a concentration of 1 µg of the chemical in 1 m³ of air. (EPA 2004)

intake

- 1) The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier, e.g., through ingestion or inhalation. (EPA 2004)
- 2) The process by which an agent crosses an outer exposure surface of a target without passing an absorption barrier, i.e., through ingestion or inhalation (see *Dose*). (IPCS 2004)

intake rate

Rate of inhalation, ingestion, and dermal contact depending on the route of exposure. For ingestion, the intake rate is simply the amount of food containing the contaminant of interest that an individual ingests during some specific time period (units of mass/time). For inhalation, the intake rate is the rate at which contaminated air is inhaled. Factors that affect dermal exposure are the amount of material that comes into contact with the skin, and the rate at which the contaminant is absorbed. (EPA 2005b)

integrated exposure assessment

Cumulative summation (over time) of the magnitude of exposure to a toxic chemical in all media. (EPA 2005b)

lifetime exposure

Total amount of exposure to a substance that a human would receive in a lifetime (usually assumed to be 70 years). (EPA 2005b, RAIS 2004)

longer-term exposure

Repeated exposure by the oral, dermal, or inhalation route for more than 30 days, up to approximately 10% of the life span in humans (more than 30 days up to approximately 90 days in typically used laboratory animal species). (EPA 2003)

margin of exposure**ACRONYM:** MOE

- 1) The LED_{10} or other point of departure divided by the actual or projected environmental exposure of interest. (EPA 2003)
- 2) The point of departure divided by the actual or projected environmental exposure of interest. (EPA 2004)
- 3) The ratio of the no-observed adverse-effect-level to the estimated exposure dose. (EPA 2005b)
- 4) Ratio of the no-observed-adverse-effect level (NOAEL) for the critical effect to the theoretical, predicted or estimated exposure dose or concentration. (IPCS/OECD 2004)

RELATED TERMS: [margin of safety](#)

maximum exposed individual**ACRONYM:** MEI

- 1) The MEI represents the highest estimated risk to an exposed individual, regardless of whether people are expected to occupy that area. (EPA 2004)
- 2) Maximally (or most) exposed individual: The person with the highest exposure in a given population. (EPA 2005b)

measure of exposure

- 1) Describes stressor existence and behavior in the environment and its contact or co-occurrence with the assessment endpoint. (EPA 1998a)
- 2) The quantitative outcome of the exposure assessment. For air toxics risk assessments, personal air concentration (or adjusted exposure concentration) is the metric of exposure

for the inhalation route of exposure and intake rate is the metric of exposure for the ingestion route of exposure. (EPA 2004)

- 3) A measurable characteristic of a stressor (such as the specific amount of mercury in a body of water) used to help quantify the exposure of an ecological entity or individual organism. (EPA 2005b)

RELATED TERMS: [metric of exposure](#)

medium intake rate

The rate at which the medium crosses the outer exposure surface of a target during ingestion or inhalation. (IPCS 2004)

metric of exposure

The quantitative outcome of the exposure assessment. For air toxics risk assessments, personal air concentration (or adjusted exposure concentration) is the metric of exposure for the inhalation route of exposure and intake rate is the metric of exposure for the ingestion route of exposure. (EPA 2004)

RELATED TERMS: [measure of exposure](#)

microenvironment

Surroundings that can be treated as homogeneous or well characterized in the concentrations of an agent (e.g., home, office, automobile, kitchen, store). This term is generally used for estimating inhalation exposures. (IPCS 2004)

multipathway exposure

When an organism is exposed to pollutants through more than one exposure pathway. One example would be exposure through both inhalation and ingestion. Another example would be ingestion of contaminated soil and ingestion of contaminated food. (EPA 2004)

RELATED TERMS: [multipathway assessment](#), [multipathway risk](#)

multiple exposure

SEE: [multipathway exposure](#)

pathway specific risk

The risk associated with exposure to a chemical agent or a mixture of chemicals via a specific pathway (e.g., inhalation of outdoor air). (EPA 2004)

per capita intake rate

The average quantity of food consumed per person in a population composed of both individuals who ate the food during a specified time period and those that did not. (EPA 2005b)

pica

- 1) Deliberate ingestion of non-nutritive substances such as soil. (EPA 1997b)
- 2) A behaviour characterized by deliberate ingestion of non-nutritive substances, such as soil. (IPCS 2001)

- 3) A behaviour characterized by deliberate ingestion of non-nutritive substances, such as soil. (IPCS 2004)

point-of-contact measurement of exposure

- 1) An approach to quantifying exposure by taking measurements of concentration over time at or near the point of contact between the chemical and an organism while the exposure is taking place. (EPA 1992)
- 2) Estimating exposure by measuring concentrations over time (while the exposure is taking place) at or near the place where it is occurring. (EPA 2005b)

point of exposure

The place where someone can come into contact with a substance present in the environment. (ATSDR 2004)

RELATED TERMS: [exposure pathway](#)

population dose

The summation of individual radiation doses received by all those exposed to the source or event being considered. (RAIS 2004, SRA 2004)

RELATED TERMS: [population exposure](#)

population exposure

SEE: [population dose](#)

reasonable worst case

- 1) A semiquantitative term referring to the lower portion of the high end of the exposure, dose, or risk distribution. The reasonable worst case has historically been loosely defined, including synonymously with maximum exposure or worst case, and assessors are cautioned to look for contextual definitions when encountering this term in the literature. As a semiquantitative term, it is sometimes useful to refer to individual exposures, doses, or risks that, while in the high end of the distribution, are not in the extreme tail. For consistency, it should refer to a range that can conceptually be described as above the 90th percentile in the distribution, but below about the 98th percentile. (compare maximum exposure range, worst case). (EPA 1992)
- 2) An estimate of the individual dose, exposure, or risk level received by an individual in a defined population that is greater than the 90th percentile but less than that received by anyone in the 98th percentile in the same population. Reasonably Available Control Technology (RACT): Control technology that is reasonably available, and both technologically and economically feasible. Usually applied to existing sources in nonattainment areas; in most cases is less stringent than new source performance standards. Reasonably Available Control Measures (RACM): A broadly defined term referring to technological and other measures for pollution control. (EPA 2005b)
- 3) A semiquantitative term referring to the lower portion of the high end of the exposure, dose, or risk distribution. The reasonable worst case has historically been loosely defined, including synonymously with maximum exposure or worst case. As a semiquantitative term, it is sometimes useful to refer to individual exposures, doses, or

risks that, while in the high end of the distribution, are not in the extreme tail. For consistency, it should refer to a range that can conceptually be described as above the 90th percentile in the distribution, but below about the 98th percentile. (EPA 2005d)

RELATED TERMS: [worst case](#)

refined exposure concentration

An estimate of exposure concentration that has been refined, usually by application of an exposure model, to better understand how people in a particular location interact with contaminated media. (EPA 2004)

RELATED TERMS: [adjusted exposure concentration](#)

route

The way a chemical or pollutant enters an organism including tap water, milk, soft drinks, alcoholic beverages, after contact, e.g., by ingestion, inhalation, or dermal and water intrinsic to purchased foods. (EPA 1997a)

route of exposure

- 1) Route: The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption. (EPA 1997a)
- 2) The way people come into contact with a hazardous substance. Three routes of exposure are breathing (inhalation), eating or drinking (ingestion), or contact with the skin (dermal contact). (ATSDR 2004)
- 3) The pathway (e.g., ingestion, inhalation, dermal) or vehicle by which a pathogen comes into contact with a host organism (e.g., food, soil, fomites, water). (ILSI 2000)

RELATED TERMS: [exposure route](#)

short-term exposure

Repeated exposure by the oral, dermal, or inhalation route for more than 24 hours, up to 30 days. (EPA 2003)

subchronic exposure

- 1) Exposure to a substance spanning approximately 10% of the lifetime of an organism. (EPA 2003)
- 2) Of intermediate duration, usually used to describe studies or levels of exposure between 5 and 90 days. (EPA 2005b, RAIS 2004)
- 3) A contact between an agent and a target of intermediate duration between acute and chronic. (Other terms, such as “less-than-lifetime exposure,” are also used.) (IPCS 2004)

RELATED TERMS: *contrast with* [acute exposure](#), [chronic exposure](#)

vector

- 1) An animate intermediary in the indirect transmission of an agent that carries the agent from a reservoir to a susceptible host. (CDC 2005)

- 2) An insect or any living carrier that transports an infectious agent from an infected individual or its wastes to a susceptible individual or its food or immediate surroundings. (MERREA 2004)

The above definitions refer to biological disease vectors. Mechanical disease vector is sometimes used to describe inanimate objects that facilitate disease transmission. In the molecular biology context a vector is a laboratory manipulated biomolecule that is used to facilitate delivery of an associated biomolecule to a tissue or organ within an organism. The most common usage of vector in genetic engineering refers to genetic material (e.g. DNA plasmid) that is ligated (chemically fused) to a gene of interest to allow transfer of that gene to a different organism.

vehicle

An inanimate intermediary in the indirect transmission of an agent that carries the agent from a reservoir to a susceptible host. (CDC 2005)

worst case

- 1) A semiquantitative term referring to the maximum possible exposure, dose, or risk, that can conceivably occur, whether or not this exposure, dose, or risk actually occurs in a specific population. (EPA 2005d)
- 2) The situation or input that forces an algorithm or data structure most time or resources. (NIST 2005)
- 3) A method of conducting an exposure assessment in which the most conservative value of each input parameter is selected. (AIHA 2000)

RELATED TERMS: [reasonable worst case](#), [maximum individual risk](#)

5.6 HOST CHARACTERIZATION AND HEALTH EFFECT TERMS

acquired immunity

A form of cellular defense which identifies certain foreign substances (antigens) as harmful to the body. For this reason, the body can acquire resistance to a particular foreign agent.

(CancerWEB 2005)

RELATED TERMS: [immunity](#)

active immunity

- 1) An organisms resistance to disease or infection, developed because the organisms immune system has produced antibodies after an infection or inoculation. (CancerWEB 2005)
- 2) Resistance developed in response to stimulus by an antigen (infecting agent or vaccine) and usually characterized by the presence of antibody produced by the host. (MERREA 2005)

RELATED TERMS: [immunity](#)

acute

- 1) Occurring over a short time (compare with chronic). (ATSDR 2004)
- 2) Referring to a health effect, sudden onset, often brief; sometimes loosely used to mean severe; referring to exposure, brief, intense, or short-term; sometimes specifically referring to a brief exposure of high intensity. (MERREA 2005)

RELATED TERMS: *contrast with* [chronic](#)

acute effect

- 1) Any toxic effect produced with a short period of time following an exposure, for example, minutes to a few days (EPA 2004)
- 2) An adverse effect on any living organism in which severe symptoms develop rapidly and often subside after the exposure stops. (EPA 2005e)
- 3) Occurring over a short time. (ATSDR 2004)
- 4) Diseases or responses with short and generally severe course (often due to high pollutant concentrations). (RAIS 2004, SRA 2004)

adverse effect

- 1) A biochemical change, functional impairment, or pathologic lesion that affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge. (EPA 2003)
- 2) (Adverse ecological effects) Changes considered undesirable because they alter valued structural or functional characteristics of ecosystems or their components. (EPA 1998a)
- 3) Change in morphology, physiology, growth, development, or life span of an organism that results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. Decisions on whether or not any effect is adverse require expert judgment. (WHO 1994)
- 4) Change in morphology, physiology, growth, development or lifespan of an organism that

results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. (ILSI 2001)

- 5) Change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences. (IPCS/OECD 2004)

RELATED TERMS: [adverse health effect](#)

Adverse effect is a general term that can be applied more broadly than the effects explicitly stated above. All adverse health effects can be considered adverse effects, however not all adverse effects are adverse health effects. Based on the definitions for the two terms, the distinction is whether health related symptoms are experienced. For example, biochemical changes, pathological lesions, and changes in morphology may be classified as adverse effects even when they are only precursors to an adverse health effect. Even though the two terms are not identical in meaning it is not unreasonable to classify disease symptoms or teratogenic effects (malformations of an embryo or fetus) as adverse effects as well as adverse health effects.

adverse health effect

- 1) A health effect from exposure to air contaminants that may range from relatively mild and temporary (e.g., eye or throat irritation, shortness of breath, or headaches) to permanent and serious conditions (e.g., birth defects, cancer or damage to lungs, nerves, liver, heart, or other organs), and which negatively affects an individual's health or well-being, or reduces an individual's ability to respond to an additional environmental challenge. (EPA 2004)
- 2) A change in body function or cell structure that might lead to disease or health problems. (ATSDR 2004)

RELATED TERMS: [adverse effect](#)

antagonistic effect

A biologic response to exposure to multiple substances that is less than would be expected if the known effects of the individual substances were added together. (ATSDR 2004)

RELATED TERMS: [additive effect](#), [synergistic effect](#)

antibody

- 1) An immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis in cells of the lymphoid series (especially plasma cells) or with antigen closely related to it. Antibodies are classified according to their mode of action as agglutinins, bacteriolysins, haemolysins, opsonins, precipitins, etc. (CancerWeb 2005)
- 2) An immunoglobulin molecule produced by B lymphoid cells with a specific amino acid sequence evoked in humans or other animals by an antigen (immunogen). These molecules are characterized by reacting specifically with the antigen in some demonstrable way, antibody and antigen each being defined in terms of the other. Antibodies may also exist naturally, without being present as a result of the stimulus provided by the introduction of an antigen; antibodies are found in the blood and body

fluids, although the basic structure of the molecule consists of two light and two heavy chains, antibodies may also be found as dimers, trimers, or pentamers. (Stedman 2005)

antigen

- 1) Substances which are capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response, that is, with specific antibodies or specifically sensitised T-lymphocytes, or both. Antigens may be soluble substances, such as toxins and foreign proteins, or particulates, such as bacteria and tissue cells; however, only the portion of the protein or polysaccharide molecule known as the antigenic determinant (epitopes) combines with antibody or a specific receptor on a lymphocyte. (CancerWeb 2005)
- 2) Any substance that, as a result of coming in contact with appropriate cells, induces a state of sensitivity and/or immune responsiveness after a latent period (days to weeks) and that reacts in a demonstrable way with antibodies and/or immune cells of the sensitized subject in vivo or in vitro. Modern usage tends to retain the broad meaning of antigen, employing the terms “antigenic determinant” or “determinant group” for the particular chemical group of a molecule that confers antigenic specificity. (Stedman 2005)

asymptomatic

- 1) Without obvious signs or symptoms of disease. (CancerWEB 2005)
- 2) Showing or causing no symptoms (a symptom is any subjective evidence of disease or of a patient's condition, i.e., such evidence as perceived by the patient; a change in a patient's condition indicative of some bodily or mental state). Note that a symptom is different from a sign, which is any objective evidence of a disease, i.e., such evidence that is perceptible to the examining physician, as opposed to the subjective sensations (symptoms) of the patient. (Dorland 1981)

RELATED TERMS: [subclinical infection](#), [carrier](#)

at-risk population

Any group who may be more susceptible to more serious symptoms or side effects from an illness than the general population. At-risk groups for foodborne illness include: very young children, pregnant women, the elderly, and people with weakened immune systems. (FDA 2001)

RELATED TERMS: [population at risk](#), [sensitive subgroups](#), [special populations](#), [subpopulation](#), [susceptible subgroups](#)

attenuation

- 1) The process by which a compound is reduced in concentration over time, through absorption, adsorption, degradation, dilution, and/or transformation. Can also be the decrease with distance of sight caused by attenuation of light by particulate pollution. (EPA 2005b)
- 2) Weakening (dilution) of the concentration, as of an antigen in a vaccine. (MERREA 2005)

bacteremia

- 1) The presence of viable bacteria circulating in the bloodstream. (CancerWeb 2005,

USDA 2004)

- 2) The presence of bacteria in the blood stream. (Queensland Health 2005)

biological medium

Any one of the major categories of material within an organism (blood, adipose tissue, breath), through which chemicals can move, be stored, or be biologically, physically, or chemically transformed. (EPA 2004)

In microbiology, biological medium is support matrix for sustaining microbiological activity or growth, (e.g., liquid broth, agar plates).

biomarker

- 1) A specific biochemical in the body which has a particular molecular feature that makes it useful for measuring the progress of disease or the effects of treatment. (CancerWeb 2005)
- 2) Indicators of changes or events in human biological systems. Biological markers of exposure refer to cellular, biochemical, or molecular measures that are obtained from biological media such as human tissues, cells, or fluids and are indicative of exposure to environmental contaminants. (NRC 1991)
- 3) Indicator of changes or events in biological systems. Biological markers of exposure refer to cellular, biochemical, analytical, or molecular measures that are obtained from biological media such as tissues, cells, or fluids and are indicative of exposure to an agent. (IPCS 2004)

chronic

- 1) Occurring over a long time (compare with acute). (ATSDR 2004)
- 2) Occurring over a long period of time, either continuously or intermittently; used to describe ongoing effects that develop only after a long exposure, especially when referring to health. (CRCWQT 2002)
- 3) Referring to a health-related state, lasting a long time; referring to exposure, prolonged or long-term, often with specific reference to low intensity. (MERREA 2005)

RELATED TERMS: *contrast with* [acute](#)

chronic effect

- 1) An effect which occurs as a result of repeated or long term (chronic) exposures. (EPA 2003)
- 2) An adverse effect on a human or animal in which symptoms recur frequently or develop slowly over a long period of time. (EPA 2005b)
- 3) An adverse effect on any living organism in which symptoms develop slowly over a long period of time or recur frequently. (EPA 2005e)

RELATED TERMS: *contrast with* [acute effect](#)

chronic health effects

- 1) An effect which occurs as a result of repeated or long term (chronic) exposures. (EPA 2003, EPA 2004)
- 2) An adverse effect on a human or animal in which symptoms recur frequently or develop

slowly over a long period of time. (EPA 2005b)

- 3) Having a persistent, recurring or long-term nature. (RAIS 2004, SRA 2004)

developmental toxicity

- 1) Adverse effects on the developing organism that may result from exposure prior to conception (either parent), during prenatal development, or postnatally until the time of sexual maturation. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth, and functional deficiency. (EPA 2003)
- 2) The potential of an agent to cause abnormal development. Developmental toxicity generally occurs in a dose-related manner, may result from short-term exposure (including single exposure situations) or from longer term low-level exposure, may be produced by various routes of exposure, and the types of effects may vary depending on the timing of exposure because of a number of critical periods of development for various organs and functional systems. The four major manifestations of developmental toxicity are death, structural abnormality, altered growth, and functional deficit. (EPA 2004)

diarrhea

An abnormally frequent discharge of semisolid or fluid fecal matter from the bowel. (Stedman 2005)

disease

- 1) Any deviation from or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of symptoms and signs and whose etiology, pathology, and prognosis may be known or unknown. (Dorland 1984)
- 2) Literally, dis-ease, the opposite of ease, when something is wrong with a bodily function. The words disease, illness, and sickness are loosely interchangeable, but are better regarded as not synonymous. Disease is a physiological/psychological dysfunction. Illness is a subjective state of the person who feels aware of not being well. Sickness is a state of social dysfunction. (MERREA 2005)
- 3) A general term describing a morbid condition which can be defined by objective, physical signs (e.g., hypertension), subjective symptoms or mental phobias, disorder of function (e.g., biochemical abnormality), or disorders of structure (anatomic or pathological change). Existence of disease may be questioned in disorder of structure without associated disorder of function. (SRA 2004)

RELATED TERMS: [syndrome](#)

duration of infectiousness

Refers to the period of time during which a host excretes infectious pathogen. In this context it does not refer to environmental stability of the pathogen. (EPA 2005f)

foodborne illness

Infection or intoxication caused by the transfer of microbial or chemical contaminants (substances that spoil or infect) from food or drinking water to a human. In most cases, the

contaminants are bacteria, parasites, or viruses. (FDA 2001)

gastroenteritis

An inflammation of the stomach and intestine resulting in diarrhoea, with vomiting and cramps when irritation is excessive. When caused by an infectious agent, it is often associated with fever. (CRCWQT 2002)

health effect

- 1) The clinical manifestation of disease associated with a specific pathogen, including symptomatic and asymptomatic infections, clinical illness, mortality, and sequelae. (ILSI 2000)
- 2) Changes in morphology, physiology growth, development or life span of an organism, which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects or other environmental influences. (KIWA 2004)
- 3) A deviation in the normal function of the human body. (MERREA 2005, RAIS 2004, SRA 2004)

health endpoint

An observable or measurable biological event used as an index to determine when a deviation in the normal function of the human body occurs. (EPA 2004)

host

- 1) In genetics, the organism, typically a bacterium, into which a gene from another organism is transplanted. In medicine, an animal infected or parasitized by another organism. (EPA 2005b)
- 2) A person or other living animal, including birds and arthropods, that affords subsistence or lodgment to an infectious agent under natural conditions. In an epidemiologic context, the host may be a population or a group. (Last 1988)
- 3) A person or other living organism that can be infected by an infectious agent under natural conditions. (CDC 2005)

illness

A condition marked by pronounced deviation from the normal healthy state. (Dorland 1981)

RELATED TERMS: [subclinical infection](#)

immune status

Immune status is a frequently used term, so it is surprising that definitions were not readily available. This may be because there are many ways to characterize the human immune system. Immune status refers to an individual's (or population's) degree of immune system functioning. Immune markers can include but are not limited to general indicators, such as T-cell count, and myriad specific markers, such as antibodies that confer acquired immunity. In addition, the general strength and specific abilities of an individual's immune system fluctuates through time. It can refer to either individual or population based measures of immunity characteristics.

immunity

The condition of being immune, the protection against infectious disease conferred either by the immune response generated by immunization or previous infection or by other nonimmunologic factors. (CancerWEB 2005)

immunocompromised

- 1) A state of reduced immune responsiveness as a result of inherited defects, infection, administration of immunosuppressive drugs, irradiation, malnutrition, or certain disease processes. (ILSI 2000)
- 2) Individuals with a weakened immune system, making them susceptible to additional infections. (USDA 2004)

Pregnancy and young or old age are also associated with weakened immune systems.

incubation period

- 1) The time from the moment of inoculation (exposure) to the development of the clinical manifestations of a particular infectious disease. (CancerWEB 2005)
- 2) time interval between invasion of the body by an infecting organism and the appearance of the first sign or symptom it causes; in a disease vector, the period between entry of the disease organism and the time at which the vector is capable of transmitting the disease to another human host. (Stedman 2005)

RELATED TERMS: [latency period](#)

individual susceptibility

The marked variability in the manner in which individuals will respond to a given exposure to a toxic agent. (MERREA 2005, SRA 2004)

infectibility

The host characteristic or state in which the host is capable of being infected. (MERREA 2005)

infection

- 1) Attachment and growth of pathogenic microorganisms, including bacteria, protozoans, viruses, and parasites, on or within the body of a human or animal. (FDA 2001)
- 2) Colonisation by a micro-organism. (KIWA 2004)
- 3) The entry and development or multiplication of an infectious agent in the body of man or animals. Infection is not synonymous with infectious disease; the result may be unapparent or manifest. The presence of living infectious agents on exterior surfaces of the body is called “infestation.” The presence of living infectious agents upon articles of apparel or soiled articles is called contamination. (MERREA 2005)
- 4) An illness or carrier state arising from colonization of foodborne microbial pathogens in the human gastrointestinal tract or other parts of the human body. Human antibodies that resist these pathogens may cause chronic complications. (USDA 2004)

RELATED TERMS: [contagious](#)

latency period

- 1) The time between first exposure to an agent and manifestation or detection of a health

effect of interest. (EPA 2003)

- 2) A period of subclinical or inapparent pathologic changes following exposure, ending with the onset of symptoms of chronic disease. (CDC 2005)
- 3) Period of time from exposure to an agent to the onset of a health effect. (MERREA 2005, RAIS 2004, SRA 2004)

latent infection

An asymptomatic infection capable of manifesting symptoms under particular circumstances or if activated. (CancerWeb 2005, Stedman 2005)

nosocomial infection

- 1) Pertaining to or originating in the hospital, said of an infection not present or incubating prior to admittance to the hospital, but generally occurring 72 hours after admittance, the term is usually used to refer to patient disease, but hospital personnel may also acquire nosocomial infection. (CancerWEB 2005)
- 2) An infection originating in a medical facility, e.g., occurring in a patient in a hospital or other health care facility in whom the infection was not present or incubating at the time of admission. Includes infections acquired in the hospital but appearing after discharge; it also includes such infections among staff. (MERREA 2005)

RELATED TERMS: [infection](#)

nutritional status

State of the body in relation to the consumption and utilization of nutrients. (CancerWEB 2005)

outcome

A term used in risk assessment that refers to an effect or consequence such as disease, illness, injury, birth defect, organ damage, death, etc. (NYS 1998)

patient isolation

The segregation of patients with communicable or other diseases for a specified time. Isolation may be strict, in which movement and social contacts are limited; modified, where an effort to control specified aspects of care is made in order to prevent cross infection; or reverse, where the patient is secluded in a controlled or germ-free environment in order to protect him or her from cross infection. (CancerWeb 2005).

population at risk

- 1) A population subgroup that is more likely to be exposed to a chemical, or is more sensitive to the chemical, than is the general population. (EPA 2005b)
- 2) A limited population that may be unique for a specific dose-effect relationship; the uniqueness may be with respect to susceptibility to the effect or with respect to the dose or exposure itself. (MERREA 2005, RAIS 2004, SRA 2004)

RELATED TERMS: [at-risk population](#), [sensitive subgroups](#), [special populations](#), [subpopulation](#), [susceptible subgroups](#)

protective immunity

State of specific resistance to infection and infectious disease resulting from prior exposure to a pathogen and/or pathogen-derived toxins. (ILSI 2000)

RELATED TERMS: [immunity](#)

secondary infection

An infection, usually septic, occurring in a person or animal already suffering from an infection of another nature. (CancerWeb 2005, Stedman 2005)

sensitive subgroups

Identifiable subsets of the general population that, due to differential exposure or susceptibility, are at greater risk than the general population to the toxic effects of a specific air pollutant (e.g., depending on the pollutant and the exposure circumstances, these may be groups such as subsistence fishers, infants, asthmatics, or the elderly). (EPA 2004)

RELATED TERMS: [at-risk population](#), [population at risk](#), [special populations](#), [subpopulation](#), [susceptible subgroups](#)

sensitivity

- 1) The ability of a test to work on people you know have the infection. More precisely $TP/(TP+FN)$, where TP is the number of true positives and FN is the number of false negatives. (Swinton 1999)
- 2) Sensitivity of a screening test is the proportion of truly diseased persons in the screened population who are identified as diseased by the screening test. Sensitivity is a measure of the probability of correctly diagnosing a case, or the probability that any given case will be identified by the test (Syn: true positive rate). (Last 1983)

RELATED TERMS: [specificity](#)

sequelae

Abnormal conditions that arise following the acute phase of a disease. For example, kidney failure may follow acute *E. coli* O157:H7 disease. (USDA 2004)

severity of illness

The degree or extent of clinical disease produced by an infectious microorganism or toxin. Severity of illness does not necessarily reflect severity of infection. (ILSI 2000)

severity of infection

The degree or extent to which a microorganism multiplies or develops in a susceptible host. Severity of infection does not necessarily determine severity of illness. (ILSI 2000)

special populations

People who might be more sensitive or susceptible to exposure to hazardous substances because of factors such as age, occupation, sex, or behaviors (for example, cigarette smoking). Children, pregnant women, and older people are often considered special populations. (ATSDR 2004)

RELATED TERMS: [at-risk population](#), [population at risk](#), [sensitive subgroups](#), [subpopulation](#), [susceptible subgroups](#)

specific immunity

The immune status in which there is an altered reactivity directed solely against the antigenic determinants (infectious agent or other) that stimulated it. (CancerWEB 2005)

RELATED TERMS: [immunity](#)

subclinical infection

- 1) An infection in which symptoms are sufficiently mild or inapparent to escape diagnosis other than by positive confirmation of the ability to transmit the infection or serologically. (CancerWeb 2005)
- 2) Infection associated with no detectable clinical signs but caused by a microorganism capable of producing clinical illness. Infection may remain subclinical, or signs and symptoms of disease may subsequently become apparent. (ILSI 2000)

RELATED TERMS: [asymptomatic](#)

subpopulation

A subset of the target population that has been identified for a specific purpose, usually requires the ability to estimate an attribute of the subpopulation. (EPA 2005c)

RELATED TERMS: [at-risk population](#), [population at risk](#), [sensitive subgroups](#), [special populations](#), [susceptible subgroups](#)

susceptibility

- 1) Increased likelihood of an adverse effect, often discussed in terms of relationship to a factor that can be used to describe a human subpopulation (e.g., life stage, demographic feature, or genetic characteristic). (EPA 2003, ATSDR 2004)
- 2) The extent to which a host is vulnerable to infection by a pathogen, taking into account a host's intrinsic and/or acquired traits that modify the risk of infection. (ILSI 2000)

susceptible subgroups

May refer to life stages, for example, children or the elderly, or to other segments of the population, for example, asthmatics or the immune-compromised, but are likely to be somewhat chemical-specific and may not be consistently defined in all cases. (EPA 2003, ATSDR 2004)

RELATED TERMS: [at-risk population](#), [population at risk](#), [sensitive subgroups](#), [special populations](#), [subpopulation](#)

syndrome

- 1) A set of signs or a series of events occurring together that often point to a single disease or condition as the cause. (CancerWeb 2005)
- 2) A group of symptoms and signs that tend to appear together and collectively characterize a disorder. (MERREA 2005)
- 3) The aggregate of symptoms and signs associated with any morbid process, and constituting together the picture of the disease. (Stedman 2005)

RELATED TERMS: [disease](#)

systemic effects

- 1) Toxic effects as a result of absorption and distribution of a toxicant to a site distant from its entry point. (EPA 2003)
- 2) Systemic effects are those that require absorption and distribution of the toxicant to a site distant from its entry point, at which point effects are produced. Most chemicals that produce systemic toxicity do not cause a similar degree of toxicity in all organs, but usually demonstrate major toxicity to one or two organs. These are referred to as the target organs of toxicity for that chemical. Systemic effects do not include cancer. (RAIS 2004)

RELATED TERMS: [systemic toxicity](#)

systemic toxicity

SEE: [systemic effects](#)

target

Any biological entity that receives an exposure or a dose (e.g., a human, a human population, or a human organ). (IPCS 2004)

target organ

The biological organ(s) most adversely affected by exposure to a chemical, physical, or biological agent. (EPA 2003)

target population

The target population is the entire group a researcher is interested in; the group about which the researcher wishes to draw conclusions. (STEPS 1997)

RELATED TERMS: [population](#)

uptake (absorption)

The process by which an agent crosses an absorption barrier (see *Dose*). (IPCS 2004)

5.7 EPIDEMIOLOGY AND SURVEILLANCE TERMS

absolute risk

An incidence rate, usually expressed per 1,000 individuals. (NZ 2002)

aggregate surveillance

The surveillance of a disease or health event by collecting summary data on groups of cases, e.g., general practitioners taking part in surveillance schemes are asked to report the number of cases of specified diseases seen over a specified period of time. (MERREA 2005)

RELATED TERMS: [public health surveillance](#), [surveillance](#)

analytic epidemiology

The aspect of epidemiology concerned with the search for health-related causes and effects. Uses comparison groups, which provide baseline data, to quantify the association between exposures and outcomes, and test hypotheses about causal relationships. (CDC 2005)

RELATED TERMS: [applied epidemiology](#)

analytical epidemiologic study

An evaluation of the association between exposure to hazardous substances and disease by testing scientific hypotheses. (EPA 2004)

applied epidemiology

- 1) The application or practice of epidemiology to address public health issues. (CDC 2005)
- 2) The application and evaluation of epidemiologic discoveries and methods in public health and health care settings. It includes applications of etiologic research, priority setting and evaluation of health programs, policies, and services. It is epidemiologic practice aimed at protecting and /or improving the health of a defined population. It usually involves identifying and investigating health problems, monitoring for changes in health status, and/or evaluating the outcomes of interventions. It is general conducted in a time frame determined by the need to protect the health of an exposed population and an administrative context that results in public health action. (MERREA 2005)

RELATED TERMS: [analytic epidemiology](#)

attack rate

- 1) The proportion of an exposed population at risk who become infected or develop clinical illness during a defined period of time. (FAO/WHO 2003b, ILSI 2000)
- 2) The proportion of a disease-free population that becomes ill during a stated or implied period of risk. (NZ 2002)

burden of illness

The sum total incidence, severity, and duration of gastrointestinal disease are known as burden of these illnesses. (Payment and Riley 2002)

carrier

- 1) The inert liquid or solid material in a pesticide product that serves as a delivery vehicle

for the active ingredient. Carriers do not have toxic properties of their own. (EPA 2005b)

- 2) Any material or system that can facilitate the movement of a pollutant into the body or cells. (EPA 2005b)
- 3) An individual who does not display the symptoms of a disease, but harbors the pathogen which causes it, or has the gene (or genes) for it, and can transmit the disease to others either through interacting with other individuals, or by passing the disease-causing gene (or genes) to offspring. (CancerWEB 2005)
- 4) A person or animal without apparent disease who harbors a specific infectious agent and is capable of transmitting the agent to others. The carrier state may occur in an individual with an infection that is inapparent throughout its course (known as asymptomatic carrier), or during the incubation period, convalescence, and postconvalescence of an individual with a clinically recognizable disease. The carrier state may be of short or long duration (transient carrier or chronic carrier). (CDC 2005)
- 5) A person or animal that harbors a specific infectious agent in the absence of discernible clinical disease and serves as a potential source of infection. (MERREA 2005)

case

- 1) In epidemiology, a countable instance in the population or study group of a particular disease, health disorder, or condition under investigation. Sometimes, an individual with the particular disease. (CDC 2005)
- 2) In epidemiology, a person in the population or study group identified as having the particular disease, health disorder, or condition under investigation. (MERREA 2005)
- 3) An individual who is ill following ingestion of food. Outbreak cases reported by CDC are determined to be contaminated on the basis of laboratory analysis and/or epidemiological evidence. Not all outbreak cases need be confirmed by laboratory analysis if there is sufficient epidemiological evidence linking them to the outbreak. (USDA 2004)

case-control study

- 1) An epidemiologic study contrasting those with the disease of interest (cases) to those without the disease (controls). The groups are then compared with respect to exposure history, to ascertain whether they differ in the proportion exposed to the chemical(s) under investigation. (EPA 2003)
- 2) A study that compares exposures of people who have a disease or condition (cases) with people who do not have the disease or condition (controls). Exposures that are more common among the cases may be considered as possible risk factors for the disease. (ATSDR 2004)
- 3) A type of observational analytic study. Enrollment into the study is based on presence (“case”) or absence (“control”) of disease. Characteristics such as previous exposure are then compared between cases and controls. (CDC 2005)
- 4) A retrospective observational study designed to determine the relationship between a particular outcome of interest (e.g., disease or condition) and a potential cause (e.g., an intervention, risk factor, or exposure). Investigators identify a group of patients with a specified outcome (cases) and a group of patients without the specified outcome (controls). Investigators then compare the histories of the cases and the controls to

determine the rate or level at which each group experienced a potential cause. As such, this study design leads from outcome (disease or condition) to cause (intervention, risk factor, or exposure). (NLM/NICHSR 2004)

- 5) An inquiry in which groups of individuals are selected in terms of whether they do (the cases) or do not (the controls) have the disease of which the etiology is to be studied, and the groups are then compared with respect to existing or past characteristics judged to be of possible relevance to the etiology of the disease. (RAIS 2004, SRA 2004)

case definition

- 1) A set of standard criteria for deciding whether a person has a particular disease or health-related condition, by specifying clinical criteria and limitations on time, place, and person. (CDC 2005)
- 2) The case definition is a standard set of criteria for deciding whether an individual should be classified as having the health condition of interest. (Gregg 1996)
- 3) A set of diagnostic criteria that must be fulfilled in order to identify a person as a case of a particular disease. Case definition can be based on clinical, laboratory, or combined clinical and laboratory criteria, or a scoring system with points for each criterion that matches the features of the disease. (MERREA 2005)

RELATED TERMS: [syndrome](#)

case-fatality ratio

A ratio of the number of deaths due to a disease to the number of cases of that disease in a specified period of time. It expresses the frequency with which affected individuals die of the disease. (SRA 2004)

case study

- 1) A medical or epidemiologic evaluation of one person or a small group of people to gather information about specific health conditions and past exposures. (EPA 2004, ATSDR 2004)
- 2) A brief fact sheet providing risk, cost, and performance information on alternative methods and other pollution prevention ideas, compliance initiatives, voluntary efforts, etc. (EPA 2005b)
- 3) An uncontrolled (prospective or retrospective) observational study involving an intervention and outcome in a single patient. (Also known as a single case report or anecdote.) (NLM/NICHSR 2004)

RELATED TERMS: [anecdotal data](#), [anecdotal evidence](#)

case-study epidemiologic study

SEE: [case study](#)

case-control epidemiologic study

SEE: [case-control study](#)

chronic study

A toxicity study designed to measure the (toxic) effects of chronic exposure to a chemical. (EPA

2003)

clinical illness

Deviation from the normal healthy state, manifested as symptomatic disease. (ILSI 2000)

clinical trial

Research study conducted with patients, usually to evaluate a new treatment or drug. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease. (CancerWEB 2005)

RELATED TERMS: [experimental study](#)

cluster

- 1) An aggregation of cases of a disease or other health-related condition, particularly cancer and birth defects, which are closely grouped in time and place. The number of cases may or may not exceed the expected number; frequently the expected number is not known. (CDC 2005)
- 2) An aggregation of relatively uncommon events or diseases in space and/or time in amounts that are believed or perceived to be greater than could be expected by chance. (MERREA 2005)

cluster investigation

A review of an unusual number, real or perceived, of health events (for example, reports of cancer) grouped together in time and location. Cluster investigations are designed to confirm case reports; determine whether they represent an unusual disease occurrence; and, if possible, explore possible causes and contributing environmental factors. (ATSDR 2004)

cohort

- 1) A group of people within a population that can be aggregated because the variation in a characteristic of interest (e.g., exposure, age, education level) within the group is much less than the group-to-group variation across the population. (EPA 2004)
- 2) A well-defined group of people who have had a common experience or exposure, who are then followed up for the incidence of new diseases or events, as in a cohort or prospective study. A group of people born during a particular period or year is called a birth cohort. (CDC 2005)
- 3) A fixed population in which membership is permanent (in contrast to a dynamic population). Also defined as a group of persons who experience a certain event in a specified period of time (e.g., a birth cohort of babies born in 1990 in New Zealand). (NZ 2002)

cohort epidemiologic study

SEE: [cohort study](#)

cohort study

- 1) An epidemiologic study comparing those with an exposure of interest to those without the exposure. These two cohorts are then followed over time to determine the differences

in the rates of disease between the exposure subjects. (EPA 2003)

- 2) A type of observational analytic study. Enrollment into the study is based on exposure characteristics or membership in a group. Disease, death, or other health-related outcomes are then ascertained and compared. (CDC 2005)
- 3) An observational study in which outcomes in a group of patients that received an intervention are compared with outcomes in a similar group, i.e., the cohort, either contemporary or historical, of patients that did not receive the intervention. In an adjusted- (or matched-) cohort study, investigators identify (or make statistical adjustments to provide) a cohort group that has characteristics (e.g., age, gender, disease severity) that are as similar as possible to the group that experienced the intervention. (NLM/NICHSR 2004)
- 4) A follow-up or longitudinal study that assesses exposure status before assessing outcome. (NZ 2002)
- 5) An epidemiologic study that observes subjects in differently exposed groups and compares the incidence of symptoms. Although ordinarily prospective in nature, such a study is sometimes carried out retrospectively, using historical data. (RAIS 2004)

RELATED TERMS: [prospective study](#), [retrospective study](#)

control

In a case-control study, comparison group of persons without disease. (CDC 2005)

RELATED TERMS: [case](#), [case-control study](#)

control group

- 1) A group used as the baseline for comparison in epidemiologic studies or laboratory studies. This group is selected because it either lacks the disease of interest (case-control group) or lacks the exposure of concern (cohort study). (EPA 2003)
- 2) The set of observations in an experiment or prospective study that do not receive the experimental treatment(s). These observations serve (a) as a comparison point to evaluate the magnitude and significance of each experimental treatment, (b) as a reality check to compare the current observations with previous observation history, and (c) as a source of data for establishing the natural experimental error. (NIST/SEMATECH 2005b)

RELATED TERMS: [reference group](#)

cross-sectional study

An epidemiological study design in which measurements of cause and effect are made at the same point in time. (SRA 2004)

death rate

- 1) An estimate of the portion of a population that dies during a specified period. (MERREA 2005)
- 2) An estimate of the proportion of the population that dies during a specified period, usually a year; the numerator is the number of people dying, the denominator is the number in the population, usually an estimate of the number at the midperiod. (Stedman 2005)

RELATED TERMS: [mortality](#)**descriptive epidemiologic study**

An evaluation of the amount and distribution of a disease in a specified population by person, place, and time. (EPA 2004)

disease surveillance

SEE: [public health surveillance](#), [surveillance](#)

endemic

- 1) Present or usually prevalent in a population or geographical area at all times, said of a disease or agent. (CancerWEB 2005)
- 2) The constant presence of a disease or infectious agent within a given geographic area or population group; may also refer to the usual prevalence of a given disease within such area or group. (CDC 2005)
- 3) Something found in a particular people or location, such as a disease that is always present in the population. (CRCWQT 2002)
- 4) Denoting a temporal pattern of disease occurrence in a population in which the disease occurs with predictable regularity with only relatively minor fluctuations in its frequency over time. (Stedman 2005)

epidemic

- 1) Occurring suddenly in numbers clearly in excess of normal expectancy, said especially of infectious diseases but applied also to any disease, injury or other health related event occurring in such outbreaks. (CancerWEB 2005)
- 2) The occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time. (CDC 2005)
- 3) Widespread outbreak of a disease, or a large number of cases of a disease in a single community or relatively small area. Disease may spread from person to person, and/or by the exposure of many persons to a single source, such as a water supply. (CRCWQT 2002)
- 4) The occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy; the word also is used to describe outbreaks of disease in animals or plants. (Stedman 2005)

RELATED TERMS: [outbreak](#); *contrast with* [endemic](#), [epizootic](#)

epidemiology

- 1) The study of the distribution and determinants of health-related states or events in specified populations. (EPA 2003)
- 2) The study of disease patterns in human populations. (EPA 2004)
- 3) Study of the distribution of disease, or other health-related states and events in human populations, as related to age, sex, occupation, ethnicity, and economic status in order to identify and alleviate health problems and promote better health. (EPA 2005b)
- 4) The study of the distribution and determinants of disease or health status in a population; the study of the occurrence and causes of health effects in humans. (ATSDR 2004)

- 5) The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems. (CDC 2005)
- 6) A branch of medicine which studies the patterns of diseases in populations, and their causes. The objective of epidemiology is to understand how and why diseases occur so that ways can be developed to prevent or reduce disease. (CRCWQT 2002)
- 7) The study of the occurrence and causes of diseases or other health-related conditions, states, or events in specified populations. One of the chief functions of this study is to identify populations at high risk for a given disease, so that the cause may be known and preventive measures implemented. (FDA 2001)
- 8) The study of the occurrence of disease, or other health-related variables, in human populations. (NZ 2002)
- 9) The study of the distribution and dynamics of diseases and injuries in human populations. Specifically, the investigation of the possible causes of a disease and its transmission. (RAIS 2004)

epidemiology triad

The traditional model of infectious disease causation. Includes three components: an external agent, a susceptible host, and an environment that brings the host and agent together, so that disease occurs. (CDC 2005)

Also referred to as the epi-triad.

epizootic

- 1) Veterinary equivalent of an epidemic. (CancerWeb 2005)
- 2) Denoting a temporal pattern of disease occurrence in an animal population in which the disease occurs with a frequency clearly in excess of the expected frequency in that population during a given time interval. An outbreak (epidemic) of disease in an animal population. (Stedman 2005)

experimental study

A study in which the investigator specifies the exposure category for each individual (clinical trial) or community (community trial), then follows the individuals or community to detect the effects of the exposure. (CDC 2005)

RELATED TERMS: [clinical trial](#)

follow-up study

SEE: [cohort study](#)

general population

The total of individuals inhabiting an area or making up a whole group. (EPA 1997a)

health outcome data

In a public health assessment, community-specific health information such as morbidity and mortality data, birth statistics, medical records, tumor and disease registries, surveillance data, and previously conducted health studies that may be collected at the local, state, and national

levels by governments, private health care organizations, and professional institutions and associations. (EPA 2004)

health outcomes study

In a public health assessment, an investigation of exposed persons designed to assist in identifying exposure or effects on public health. Health studies also define the health problems that require further inquiry by means of, for example, a health surveillance or epidemiologic study. (EPA 2004)

herd immunity

- 1) An estimate of exposure, or dose level received anyone in a defined population that is greater than the 90th percentile of all individuals in that population, but less than the exposure at the highest percentile in that population. A high end risk descriptor is an estimate of the risk level for such individuals. Note that risk is based on a combination of exposure and susceptibility to the stressor. (EPA 2005b)
- 2) Resistance of a group to a pathogen due to immunity of a large proportion of the group to that pathogen. (NLM 2005)
- 3) The resistance of a group to invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group. The resistance is a product of the number susceptible and the probability that those who are susceptible will come into contact with an infected person. (CDC 2005)
- 4) The immunity of a group or community. The resistance of a group to invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group. The resistance is a product of the number susceptible and the probability that those who are susceptible will come into contact with an infected person. (MERREA 2005)

high-risk community

A community located within the vicinity of numerous sites of facilities or other potential sources of environmental exposure/health hazards which may result in high levels of exposure to contaminants or pollutants. (EPA 2005b)

incidence

- 1) The number of new cases of a disease that develop within a specified population over a specified period of time. (EPA 2003)
- 2) The number of new cases of disease in a defined population over a specific time period. (ATSDR 2004)
- 3) The rate of occurrence of new cases of a disease or condition in a population at risk during a given period of time, usually one year. (NLM/NICHSR 2004)
- 4) The number of new cases of a disease in a population over a period of time. (RAIS 2004, SRA 2004)
- 5) A measure of the magnitude of a disease, usually expressed as the number of new cases of a disease per 100,000 individuals in the U.S. population in a one-year period. (USDA 2004)

RELATED TERMS: *contrast with* [prevalence](#)

incidence rate

- 1) The ratio of new cases within a population to the total population at risk given a specified period of time. (EPA 2003)
- 2) A measure of the frequency with which an event, such as a new case of illness, occurs in a population over a period of time. The denominator is the population at risk; the numerator is the number of new cases occurring during a given time period. (CDC 2005)

index case (proband)

- 1) A person who first draws attention to their family. For example, if my eye doctor discovers I have glaucoma and subsequently other cases of glaucoma are found in my family, I am the index case. Also called the proband (if male) or probanda (if female). (CancerWeb 2005)
- 2) In human genetics, the patient or member of the family that brings a family under study. (Stedman 2005)

Note: Index case can also refer to the initial case in a larger population and not just within a family.

instrument error

A type of non-sampling error caused by the survey instrument (or questionnaire) itself, such as unclear wording, asking respondents for information they are unable to supply or the instrument being changed in some way during the course of the research. (ESOMAR 2001)

RELATED TERMS: [survey](#)

longitudinal epidemiologic study

SEE: [cohort study](#)

matching

- 1) The process of making a study group and a comparison group in an epidemiological study comparable with respect to extraneous or confounding factors such as age, sex, weight, etc. (CancerWEB 2005)
- 2) In a retrospective study, a method for identifying a comparison group. Matching pairs observational unit: each unit that has both trait-of-interest A and nuisance effects B,C,... with another unit that lacks trait-of-interest A, yet still shares B,C,... Low yielding lots (trait-of-interest is yield) are in this way compared to well yielding lots of the same product started at about the same time. Matches in this way are more sensitive to key causal differences (for example, in the particular equipment set used) than would occur from taking “matches” from all available lots. Matching is a way of implementing commonality studies. Matching is a kind of blocking for retrospective studies. (NIST/SEMATECH 2005b)

RELATED TERMS: [case-control study](#), [retrospective study](#)

morbidity

- 1) State of being ill or diseased. Morbidity is the occurrence of a disease or condition that alters health and quality of life. (ATSDR 2004)

- 2) Any departure, subjective or objective, from a state of physiological or psychological well-being. (CDC 2005)
- 3) A departure from a state of physical or mental well-being, resulting from disease or injury. Frequently used only if the affected individual is aware of the condition. Awareness itself connotes a degree of measurable impact. Frequently, but not always, there is a further restriction that some action has been taken such as restriction of activity, loss of work, seeking of medical advice, etc. (MERREA 2004, RAIS 2004, SRA 2004)

morbidity rate

The number of illnesses or cases of disease in a population in relation to the total population. (NYS 1998)

RELATED TERMS: [incidence](#)

mortality

- 1) Death. Usually the cause (a specific disease, a condition, or an injury) is stated. (ATSDR 2004)
- 2) Death; the death rate; ratio of number of deaths to a given population. (RAIS 2004, SRA 2004)

RELATED TERMS: [death rate](#)

mortality rate

- 1) A measure of the frequency of occurrence of death in a defined population during a specified interval of time. (CDC 2005)
- 2) The number of deaths that occur in a given population during a given time interval; usually deaths per 10^3 or 10^5 people per year. Can be age, sex, race, and cause specific. (MERREA 2005, RAIS 2004, SRA 2004)

RELATED TERMS: [death rate](#)

notifiable disease

- 1) Diseases, usually of an infectious nature, whose occurrence is required by law to be made known to a health officer or local government authority. (CancerWEB 2005)
- 2) A disease that, by statutory requirements, must be reported to the public health authority in the pertinent jurisdiction when the diagnosis is made. A disease deemed of sufficient importance to the public health to require that its occurrence be reported health authorities. The reporting to public health authorities of communicable diseases is, unfortunately, very incomplete. The reasons for this include diagnostic inexactitude, the desire of patients and physicians to conceal the occurrence of conditions carrying a social stigma, and the indifference of physicians to the usefulness of information about such diseases as hepatitis, influenza, and measles. Notifications provide the starting point for investigations into the failure of preventive measures, such immunizations, for tracing sources of infection, for finding common vehicles of infection, for describing the geographic clustering of infection, and for various other purposes, depending upon the particular disease. (MERREA2005)

observational epidemiologic study

A study in which the investigators do not manipulate the use of, or deliver, an intervention (e.g., do not assign patients to treatment and control groups), but only observe patients who are (and sometimes patients who are not as a basis of comparison) exposed to the intervention, and interpret the outcomes. These studies are more subject to selection bias than experimental studies such as randomized controlled trials. (NLM/NICHSR 2004)

RELATED TERMS: [observational study](#)

observational study

A study in which the investigators do not manipulate the use of, or deliver, an intervention (e.g., do not assign patients to treatment and control groups), but only observe patients who are (and sometimes patients who are not as a basis of comparison) exposed to the intervention, and interpret the outcomes. These studies are more subject to selection bias than experimental studies such as randomized controlled trials. (NLM/NICHSR 2004)

RELATED TERMS: [observational epidemiologic study](#)

occurrence

In epidemiology, a general term describing the frequency of a disease or other attribute or event in a population without distinguishing between incidence and prevalence. (MERREA 2005)

Occurrence is also used in the context of pathogen occurrence, which is a step in exposure analysis in the MRA Protocol.

odds ratio

ACRONYM: OR

- 1) A relative measure of the difference in exposure between the diseased (cases) and not diseased (controls) individuals in a case-control study. The OR is interpreted similarly to the relative risk. (EPA 2003)
- 2) A measure of association that quantifies the relationship between an exposure and health outcome from a comparative study; also known as the cross-product ratio. (CDC 2005)
- 3) A measure of treatment effect that compares the probability of a type of outcome in the treatment group with the outcome of a control group, i.e., $[Pt \div (1 - Pt)] [Pc \div (1 - Pc)]$. For instance, if the results of a trial were that the probability of death in a control group was 25% and the probability of death in a treatment group was 10%, the odds ratio of survival would be $[0.10 \div (1.0 - 0.10)] \div [(0.25 \div (1.0 - 0.25))] = 0.33$. (NLM/NICHSR 2004)

outbreak

- 1) Synonymous with epidemic. Sometimes the preferred word, as it may escape sensationalism associated with the word epidemic. Alternatively, a localized as opposed to generalized epidemic. (CDC 2005)
- 2) An epidemic limited to localized increase in the incidence of a disease, e.g., in a village, town, or closed institution. (MERREA 2005)

RELATED TERMS: [epidemic](#)

outbreak data

CDC data on foodborne disease outbreaks define an outbreak as an incident in which two or

more persons experienced a similar illness after ingestion of a common food, and epidemiologic analysis implicated a food as the source of the illness. There are two exceptions, botulism and chemical poisoning, in which one case constitutes an outbreak. (USDA 2004)

outbreak, foodborne

An incident in which two or more cases of a similar illness result from eating the same food. (FDA/CFSAN 2001)

pandemic

- 1) A widespread epidemic throughout an area, nation or the world. (EPA 2005b)
- 2) An epidemic that affects a wide geographic area. (CancerWeb 2005)
- 3) An epidemic occurring over a very wide area (several countries or continents) and usually affecting a large proportion of the population. (CDC 2005)
- 4) An epidemic occurring worldwide, or over a very wide area, crossing international boundaries, and usually affecting a large number of people. (MERREA 2005)
- 5) Denoting a disease affecting or attacking the population of an extensive region, country, continent, global; extensively epidemic. (Stedman 2005)

RELATED TERMS: [epidemic](#)

person-time

A unit of measurement combining persons and time, used as denominator in instantaneous incidence rates. It is the sum of individual units of time that the persons in the study population have been exposed to the condition of interest. A variant is person-distance, e.g., as in passenger-miles. The most frequently used person-time is person-years. With this approach, each subject contributes only as many years of observation to the population at risk as he is actually observed; if he leaves after one year, he contributes one person-year; if after ten, ten person-years. The method can be used to measure incidence over extended and variable time periods. (Last 1983)

person-year

The sum of the number of years each person in the study population is at risk; a metric used to aggregate the total population at risk assuming that 10 people at risk for one year is equivalent to 1 person at risk for 10 years. (RAIS 2004, SRA 2004)

population risk

Population risk refers to an estimate of the extent of harm for the population or population segment being addressed. It often refers to an analysis of the number of people living at a particular risk or hazard level. (EPA 2004)

premature death

A death that occurs before statistical expectation, usually attributable to a specific cause, and usually referring to deaths statistically estimated in a population rather than to individuals. (RAIS 2004, SRA 2004)

prevalence

- 1) The proportion of disease cases that exist within a population at a specific point in time, relative to the number of individuals within that population at the same point in time. (EPA 2003)
- 2) The number of existing disease cases in a defined population during a specific time period. (ATSDR 2004)
- 3) The number or proportion of cases or events or conditions in a given population. (CDC 2005)
- 4) The number of events, e.g., instances of a given disease or other condition, in a given population at a designated time. (MERREA 2005)
- 5) The number of people in a population with a specific disease or condition at a given time, usually expressed as a ratio of the number of affected people to the total population. (NLM/NICHSR 2004)
- 6) The number of existing cases in a population who have the disease at a given point (or during a given period) of time. (RAIS 2004, SRA 2004)
- 7) The total number of cases of a given disease at a particular point in time, includes new (i.e., incidence) as well as chronic cases. (USDA 2004)

RELATED TERMS: *contrast with* [incidence](#)

prevalence rate

The proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified period of time. (CDC 2005)

prevalence survey

The measure of the current level of disease (s) or symptoms and exposures through a questionnaire that collects self-reported information from a defined population. (ATSDR 2004)

RELATED TERMS: [survey](#)

Prevalence surveys can also include diagnostic testing (often serology) to assess disease/infection status; although most also include a questionnaire as a component. Prevalence surveys in wild animal populations obviously do not include questionnaires.

primary contact

Person(s) in direct contact or associated with a communicable disease case. (MERREA 2005)

RELATED TERMS: [contact](#), [direct contact](#)

primary transmission

Direct or indirect transfer of a food- or waterborne pathogen from a contaminated medium to a susceptible host, whether or not disease is produced. (ILSI 2000)

proportionate mortality ratio

ACRONYM: PMR

- 1) The proportion of deaths due to the disease of interest in the exposed population divided by the proportion of deaths due to the disease of interest in the unexposed or reference population. It is frequently converted to a percent by multiplying the ratio by 100. (EPA 2003)

- 2) The fraction of all deaths from a given cause in the study population divided by the same fraction from a standard population. A tool for investigating cause-specific risks when only data on deaths are available. If data on the population at risk are also available, standardized mortality ratios are preferred. (RAIS 2004, SRA 2004)

prospective epidemiologic study

SEE: [prospective study](#)

prospective study

- 1) An epidemiologic study comparing those with an exposure of interest to those without the exposure. These two cohorts are then followed over time to determine the differences in the rates of disease between the exposure subjects. (EPA 2003)
- 2) A study in which the investigators plan and manage the intervention of interest in selected groups of patients. As such, investigators do not know what the outcomes will be when they undertake the study. (NLM/NICHSR 2004)
- 3) A study in which the disease events to be measured have not occurred when the study begins, and so study participants have no foreknowledge of their possible involvement. Both follow-up studies and case-control studies can be prospective with respect to their accumulation of cases. (NZ 2002)
- 4) An inquiry in which groups of individuals are selected in terms of whether they are or are not exposed to certain factors, and then followed over time to determine differences in the rate at which disease develops in relation to exposure to the factor. Also called cohort study. (RAIS 2004, SRA 2004)

RELATED TERMS: [cohort study](#); *contrast with* [retrospective study](#)

public health surveillance

- 1) The ongoing, systematic collection, analysis, and interpretation of health data. This activity also involves timely dissemination of the data and use for public health programs. (ATSDR 2004)
- 2) The systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, to gain knowledge of the pattern of disease occurrence and potential in a community, in order to control and prevent disease in the community. (CDC 2005)
- 3) The systematic collection, analysis and interpretation of the health data that is used to plan, implement, and evaluate public health programs. Also used to determine the need for public health action. (MERREA 2005)

RELATED TERMS: [surveillance](#), [disease surveillance](#)

rate

- 1) An expression of the frequency with which an event occurs in a defined population. (CDC 2005)
- 2) In epidemiology, "rate" has special usage; it is the frequency with which an event occurs in a defined population, at or over a specified period of time. A rate is therefore a ratio, and includes proportions. (NZ 2002)

reference group

SEE: [control group](#)

respondent error

- 1) A type of non-sampling error caused by respondents intentionally or unintentionally providing incorrect answers to research questions. (ESOMAR 2001)
- 2) In surveys, a component of measurement error that results from the respondent deliberately or inadvertently answering incorrectly. (NIST/SEMATECH 2005b)

RELATED TERMS: [survey](#)

retrospective study

- 1) A kind of nonexperimental study in which all the phenomenon investigated occurs prior to the onset of the study. Further, the samples of retrospective studies are usually chosen by the value the responses take. This latter point creates special conceptual issues regarding causality, and the composition of comparison samples (see matches) is especially important. Advantages of retrospective samples is that they allow one to investigate phenomena that are either unlikely or undesirable to occur in the future; further, since all key events occur in the past, retrospective studies can often be undertaken economically. (NIST/SEMATECH 2005b)
- 2) A study in which investigators select groups of patients that have already been treated and analyze data from the events experienced by these patients. These studies are subject to bias because investigators can select patient groups with known outcomes. (NLM/NICHSR 2004)

RELATED TERMS: [bias](#), [cohort study](#), [retrospective study](#); *contrast with* [prospective study](#)

secondary attack rate

- 1) A measure of the frequency of new cases of a disease among the contacts of known cases. (CDC 2005)
- 2) The number of cases of an infection that occur among contacts within the incubation period following exposure to a primary case in relation to the total number of exposed contacts. (MERREA 2005)

RELATED TERMS: [secondary transmission](#)

secondary spread

SEE: [secondary transmission](#)

secondary transmission

Direct or indirect propagation of a pathogen from an infected person (with or without clinical illness) to additional people. (ILSI 2000)

seroepidemiology

An epidemiology study or activity based on serologic testing of characteristic change in the serum level of specific antibodies. Latent, subclinical infections and carrier states can thus be detected, in addition to clinically overt cases. (MERREA 2004)

specificity

Specificity of a screening test is the proportion of truly nondiseased persons who are so identified by the screening test. It is a measure of the probability of correctly identifying a nondiseased person with a screening test. (Last 1983)

RELATED TERMS: [sensitivity](#)

standardized mortality ratio

ACRONYM: SMR

- 1) This is the relative measure of the difference in risk between the exposed and unexposed populations in a cohort study. The SMR is similar to the relative risk in both definition and interpretation. This measure is usually standardized to control for any differences in age, sex, and/or race between the exposed and reference populations. It is frequently converted to a percent by multiplying the ratio by 100. (EPA 2003)
- 2) The ratio of observed deaths in a population to the expected number of deaths as derived from rates in a standard population with adjustment of age and possibly other factors such as sex or race. (RAIS 2004, SRA 2004)

surveillance

Systematic ongoing collection, collation, and analysis of data and the timely dissemination of information to those who need to know so that action can be taken. Surveillance is the essential feature of epidemiological practice. (MERREA 2005)

RELATED TERMS: [public health surveillance](#), disease surveillance

survey

- 1) Surveys involve a (statistically) large number of interviews with respondents, using pre-designed questionnaires. (ESOMAR 2001)
- 2) A method of data collection that involves asking a fixed set of questions from selected individuals. Key issues involve questionnaire development, (ideally random) sample selection, and nonresponse management. (NIST/SEMATECH 2005b)

transmission of infection

- 1) Any mode or mechanism by which an infectious agent is spread through the environment or to another person. (CDC 2005)
- 2) Transmission of infectious agents. Any mechanism by which an infectious agent is spread from a source or reservoir to another person. Direct transmission is the direct and essentially immediate transfer of infectious agents to a receptive portal of entry through which human or animal infection may take place. This may be by direct contact such as touching, kissing, biting, or sexual intercourse, or by the direct projection (droplet spread) of droplet spray onto the conjunctiva or onto the mucous membranes of the eyes, nose, or mouth. It may also be by direct exposure of susceptible tissue to an agent in soil, compost, or decaying vegetable matter or by the bite of a rabid animal. Indirect transmission is by vector or air; the latter is subdivided into droplet or dust. (MERREA 2005)

RELATED TERMS: [transmissible](#), [secondary transmission](#)

zoonoses

- 1) An infectious disease that is transmissible under normal conditions from animals to humans. (CDC 2005)
- 2) Diseases and infections that are naturally transmitted between vertebrate animals and humans. (CRCWQT 2002)
- 3) Infections in animals that can be transmitted to humans. (FDA 2001)
- 4) A disease that can be passed from animals, whether wild or domesticated, to humans. (MERREA 2005)
- 5) Diseases of humans transmitted from animals. (NZ 2002)
- 6) A human disease that originates from an animal. (Jones 2006)

5.8 DOSE-RESPONSE TERMS

additive dose

The overall result of exposure to two or more chemicals, when each chemical behaves as a concentration or dilution of the other chemicals in the mixture. The response of the combination is the response expected from the equivalent dose of an index chemical. The equivalent dose is the sum of component doses scaled by their toxic potency relative to the index chemical. (EPA 2004)

additive effect

A biologic response to exposure to multiple substances that equals the sum of responses of all the individual substances added together. (ATSDR 2004)

RELATED TERMS: [antagonistic effect](#), [synergistic effect](#)

benchmark concentration

ACRONYM: BMC

SEE: [benchmark dose](#)

benchmark concentration lower confidence limit

ACRONYM: BMCL

SEE: [benchmark dose lower confidence limit](#)

benchmark dose

ACRONYM: BMD

A dose or concentration that produces a predetermined change in response rate of an adverse effect (called the benchmark response or BMR) compared to background. (EPA 2003)

benchmark dose lower confidence limit

ACRONYM: BMDL

A statistical lower confidence limit on the dose or concentration at the BMD. (EPA 2003)

benchmark response

ACRONYM: BMR

An adverse effect, used to define a benchmark dose from which an RfD (or RfC) can be developed. The change in response rate over background of the BMR is usually in the range of 5-10%, which is the limit of responses typically observed in well-conducted animal experiments. (EPA 2003)

biologically based dose-response model

ACRONYM: BBDR model

A predictive model that describes biological processes at the cellular and molecular level linking the target organ dose to the adverse effect. (EPA 2003)

concentration-effect relationship

Relationship between the exposure, expressed in concentration, of a given organism, system, or

(sub) population to an agent in a specific pattern during a given time and the magnitude of a continuously-graded effect to that organism, system, or (sub) population. (IPCS/OECD 2004)

RELATED TERMS: [effect assessment](#), [dose-response relationship](#), [exposure-response](#)

cumulative dose

The total dose resulting from repeated exposures of ionizing radiation to an occupationally exposed worker to the same portion of the body, or to the whole body, over a period of time (see 10 CFR 20.1003). (RAIS 2004)

Note: It may be necessary to also determine cumulative dose for microbial pathogens if there is more than one source of exposure during a finite time or if there are multiple exposures to a single source. For microbial pathogens the cumulative dose period may be short (over hours or a day).

dose

- 1) The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism.
 - (a) The POTENTIAL DOSE is the amount ingested, inhaled, or applied to the skin.
 - (b) The APPLIED DOSE is the amount presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism).
 - (c) The ABSORBED DOSE is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of the skin, lung, and digestive tract) through uptake processes.
 - (d) INTERNAL DOSE is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries.
 - (e) The amount of the chemical available for interaction by any particular organ or cell is termed the DELIVERED or BIOLOGICALLY EFFECTIVE DOSE for that organ or cell. (EPA 1997a, EPA 2003, EPA 2004, EPA 2005a)
- 2)
 - (a) The actual quantity of a chemical administered to an organism or to which it is exposed.
 - (b) The amount of a substance that reaches a specific tissue (e.g., the liver).
 - (c) The amount of a substance available for interaction with metabolic processes after crossing the outer boundary of an organism.
- 3) In terms of monitoring exposure levels, the amount of a toxic substance taken into the body over a given period of time. (EPA 2005e)
- 4)
 - (a) (for non-radioactive chemicals) The amount of a substance to which a person is exposed over some time period. Dose is a measurement of exposure. Dose is often expressed as milligram (amount) per kilogram (a measure of body weight) per day (a measure of time) when people eat or drink contaminated water, food, or soil. In general, the greater the dose, the greater the likelihood of an effect. An “exposure dose” is how much of a substance is encountered in the environment. An “absorbed dose” is the amount of a substance that actually got into the body through the eyes, skin, stomach, intestines, or lungs.
 - (b) (for radioactive chemicals) The radiation dose is the amount of energy from radiation that is actually absorbed by the body. This is not the same as measurements of the amount of radiation in the environment. (ATSDR 2004)

- 5) The amount of a pathogen that enters or interacts with an organism. (FAO/WHO 2003b, ILSI 2000)
Includes discrete single doses and continuous and multiple exposures. (ILSI 2000 text)
- 6) The amount of a toxic component or the number of a pathogen that is ingested or interacts with an organism (host). (FDA 2002)
- 7) Total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population. (IPCS/OECD 2004)
- 8) The amount or concentration of undesired matter or energy deposited at the site of effect. (SRA 2004)
- 9) The amount of agent that enters a target after crossing an exposure surface. If the exposure surface is an absorption barrier, the dose is an absorbed dose/uptake dose (see uptake); otherwise, it is an intake dose (see intake). (See introductory comments.) (IPCS 2004)

RELATED TERMS: [absorbed dose](#), [administered dose](#), [applied dose](#), [potential dose](#) (EPA 2005b)

dose adjustment

Modification of doses used in animal experimentation to equivalent levels for human beings. The usual method is to calculate the ratio of body weights raised to some power, which is roughly equivalent to the ratio of surface areas; a simple ratio of body weights has also been used. (AIHA 2000)

dose rate

- 1) Dose per unit time, for example in mg/day, sometimes also called dosage. Dose rates are often expressed on a per-unit body-weight basis, yielding units such as mg/kg/day (mg/kg-day). They are also often expressed as averages over some time period, for example a lifetime (EPA 1992).
- 2) In exposure assessment, dose per time unit (e.g., mg/day), sometimes also called dosage (EPA 1997b)
- 3) Dose per unit time. (IPCS 2004)

dose-effect relationship

- 1) Relationship between the total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the magnitude of a continuously-graded effect to that organism, system or (sub)population. (IPCS/OECD 2004)
- 2) Determination of the quantitative relationship between exposure to a particular substance or activity and the incidence or severity of an effect. Dose-response assessment evaluates the conditions under which the effect might occur and considers factors that influence relationships, such as intensity and pattern of exposure and age and lifestyle variables that could affect susceptibility. Such assessments also can involve extrapolation of high-dose responses to low-dose responses and from animal responses to human responses. The development of this relationship may involve the use of mathematical models. (NYS 1998)
- 3) The relationship between dose (usually an estimate of dose) and the gradation of the effect in a population, that is a biological change measured on a graded scale of severity,

although at other times one may only be able to describe a qualitative effect that occurs within some range of exposure levels. (RAIS 2004, SRA 2004)

RELATED TERMS: [effect assessment](#), [dose-response relationship](#), [concentration-effect relationship](#)

dose-related effect

Any effect to an organism, system or (sub) population as a result of the quantity of an agent administered to, taken up or absorbed by that organism, system, or (sub) population. (IPCS/OECD 2004)

dose-response

- 1) Shifts in toxicological responses of an individual (such as alterations in severity) or populations (such as alterations in incidence) that are related to changes in the dose of any given substance. (EPA 2005b)
- 2) How an organism's response to a toxic substance changes as its overall exposure to the substance changes. For example, a small dose of carbon monoxide may cause drowsiness; a large dose can be fatal. (EPA 2005e)
- 3) The relationship between the amount of exposure [dose] to a substance and the resulting changes in body function or health (response). (ATSDR 2004)
- 4) The quantitative relationship between the dose of an agent and an effect caused by the agent. (CRCWQT 2002)
- 5) A relationship in which a change in amount, intensity, or duration of exposure to a pathogen is associated with a change in the manifestation and magnitude of human health effects. (ILSI 2000)
- 6) Relationship between the amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the change developed in that organism, system or (sub) population in reaction to the agent. Synonymous with dose-response relationship. (IPCS/OECD 2004)
- 7) A correlation between a quantified exposure (dose) and the proportion of a population that demonstrates a specific effect (response). (RAIS 2004, SRA 2004)

RELATED TERMS: [dose-effect relationship](#), [effect assessment](#), [concentration-effect relationship](#), [exposure-response](#)

dose-response analysis

The process of characterizing the relation between pathogen dose, infectivity, and the manifestation and magnitude of health effects in an exposed population, including estimating the incidence of the health effects as a function of exposure to the pathogen. (ILSI 2000)

RELATED TERMS: [dose-response assessment](#)

dose-response assessment

- 1) A determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence or change in level of response, percent response in groups of subjects (or populations), or the probability of occurrence or change in level of response within a population. (EPA 2003)

- 2) A determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or as the probability of occurrence within a population. (EPA 2004)
- 3) (a) Estimating the potency of a chemical.
(b) In exposure assessment, the process of determining the relationship between the dose of a stressor and a specific biological response.
(c) Evaluating the quantitative relationship between dose and toxicological responses. (EPA 2005b)
- 4) The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent, and the severity and/or frequency of associated adverse health effects (response). (CAC 1999, CAC 2003, FAO/WHO 2003b)
- 5) The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of an effect. (FDA 2002)
- 6) Analysis of the relationship between the total amount of an agent administered to, taken up or absorbed by an organism, system or (sub)population and the changes developed in that organism, system or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose-Response Assessment is the second of four steps in risk assessment. (IPCS/OECD 2004)
- 7) The determination of the relationship between the magnitude of exposure (dose) to a microbiological agent and the severity and/or frequency of the associated adverse health effects (response). (KIWA 2004)
- 8) The process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. It takes account of intensity of exposure, age pattern of exposure, and possibly other variables that might affect response, such as sex, lifestyle, and other modifying factors. A dose-response assessment usually requires extrapolation from high to low dose and extrapolation from animals to humans. A dose-response assessment should describe and justify the methods of extrapolation used to predict incidence and should characterize the statistical and biologic uncertainties in these methods (NRC 1983).
- 9) The process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. (RAIS 2004, SRA 2004)

RELATED TERMS: [hazard characterization](#), [dose-effect relationship](#), [effect assessment](#), [dose-response relationship](#), [concentration-effect relationship](#)

dose-response curve

- 1) A graphical representation of the quantitative relationship between administered, applied, or internal dose of a chemical or agent, and a specific biological response to that chemical or agent. (EPA 2004)
- 2) Graphical representation of the relationship between the dose of a stressor and the biological response thereto. (EPA 2005b)
- 3) A mathematical relationship between the dose administered or received and the incidence

of adverse health effects in the exposed population; toxicity values are derived from this relationship (AIHA 2000).

- 4) Graphical presentation of a dose-response relationship. (IPCS/OECD 2004)

dose-response relationship

- 1) The resulting biological responses in an organ or organism expressed as a function of a series of doses. (EPA 1997a)
- 2) The relationship between a quantified exposure (dose) and the proportion of subjects demonstrating specific biologically significant changes in incidence and/or in degree of change (response). (EPA 2003)
- 3) The quantitative relationship between the amount of exposure to a substance and the extent of toxic injury or disease produced. (EPA 2005b)
- 4) Relationship between the amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the change developed in that organism, system or (sub) population in reaction to the agent. (IPCS/OECD 2004)

RELATED TERMS: [dose-effect relationship](#), [effect assessment](#), [concentration-effect relationship](#)

infectious dose

The number of organisms that make individuals ill or carriers. In reality, there is a probability distribution associated with different pathogen exposure levels. (USDA 2004)

RELATED TERMS: [minimum infective dose](#)

infective dose_x

ACRONYM: ID_x

This term applies to the dose that will cause infection in x% of the population receiving the dose (e.g., ID₅₀ for 50% of population). (Microbial AWQC Methodology)

RELATED TERMS: [lethal dose](#)

internal dose

In exposure assessment, the amount of a substance penetrating the absorption barriers (e.g., skin, lung tissue, gastrointestinal tract) of an organism through either physical or biological processes. (EPA 2004, EPA 2005b)

lethal dose

ACRONYM: LD

This term applies to the dose that will cause death in x% of the population receiving the dose (e.g., LD₅₀ for 50% of population). (Microbial AWQC Methodology)

RELATED TERMS: [lethal dose-50](#), [infective dose](#)

lethal dose-50

ACRONYM: LD₅₀

The dose of a toxicant or microbe that will kill 50 percent of the test organisms within a designated period. The lower the LD₅₀, the more toxic the compound. (EPA 2005b, EPA 2005e)

lowest acceptable daily dose

The largest quantity of a chemical that will not cause a toxic effect, as determined by animal studies. (EPA 2005b)

minimum infective dose**ACRONYM:** MID

This term was intended to indicate the lowest dose that would cause infection in an individual and assumed that there was a threshold dose. This term generally considered to be obsolete because one microorganism is believed to be capable of causing infection in a susceptible individual. However, it should be noted that infection does not imply symptomatic illness. (EPA 2005f)

RELATED TERMS: *contrast with* [quorum sensing](#)

non-linear dose response

- 1) A pattern of frequency or severity of biological response that does not vary directly with the amount of dose of an agent. (EPA 2003)
- 2) The term “nonlinear” is used in the Guidelines for Carcinogenic Risk Assessment in a narrower sense than its usual meaning in the field of mathematical modeling. In the cancer guidelines, the term “nonlinear” refers to threshold models (which show no response over a range of low doses that include zero) and some nonthreshold models (e.g., a quadratic model, which shows some response at all doses above zero). In the cancer guidelines, a nonlinear model is one whose slope is zero at (and perhaps above) a dose of zero. (EPA 2005a)

non-threshold effect

- 1) An effect (usually an adverse health effect) for which there is no exposure level below which the effect is not expected to occur. (EPA 2004)
- 2) A non-threshold model presumes that one organism can lead to infection. (ILSI 2000 text)

RELATED TERMS: *contrast with* [threshold effect](#)

point of departure**ACRONYM:** POD

- 1) The dose-response point that marks the beginning of a low-dose extrapolation. This point can be the lower bound on dose for an estimated incidence or a change in response level from a dose-response model (BMD), or a NOAEL or LOAEL for an observed incidence, or change in level of response. (EPA 2003)
- 2) A point of departure marks the beginning of extrapolation to lower doses. The POD is an estimated dose (usually expressed in human-equivalent terms) near the lower end of the observed range, without significant extrapolation to lower doses. (EPA 2005a)

potential dose

The amount of a compound contained in material swallowed, breathed, or applied to the skin. (EPA 2004)

probability of illness

The likelihood that a susceptible host will develop symptomatic disease given sufficient exposure to a particular microorganism. (ILSI 2000)

probability of infection

The likelihood that a particular microorganism will successfully establish itself in a given host or population. (ILSI 2000)

response

Change developed in the state or dynamics of an organism, system or (sub) population in reaction to exposure to an agent. (IPCS/OECD 2004)

threshold

- 1) The dose or exposure below which no deleterious effect is expected to occur. (EPA 2003)
- 2) Threshold Dose/Threshold - The lowest dose of a chemical at which a specified measurable effect is observed and below which it is not observed. (EPA 2004, EPA 2005b)
- 3) Threshold Dose of a substance or exposure concentration below which a stated effect is not observed or expected to occur (disease). (WHO 1999)
- 4) Dose or exposure concentration of an agent below that a stated effect is not observed or expected to occur. (IPCS/OECD 2004)
- 5) A pollutant concentration [or dose], below which no deleterious effect occurs. (RAIS 2004, SRA 2004)
- 6) A threshold dose is a dose level below which there is no effect of radiation on the biological response. It is often difficult to distinguish between a threshold and a linear-quadratic dose response where the response changes only slightly at low doses. A threshold model postulates that radiation does not cause the effect at any level below the threshold. Radiation thresholds are generally thought to be limited to acute (short-term) effects that are called deterministic, because they require depletion of certain cells in the body to below a critical number in a given organ or tissue. These effects include radiation sickness (nausea and vomiting), infection and bleeding, and loss of hair. (RERF 1999)

RELATED TERMS: [non-linear dose response](#), [minimum infective dose](#)

threshold effect

An effect (usually an adverse health effect) for which there is an exposure level below which the effect is not expected to occur. (EPA 2004, EPA 2005b)

RELATED TERMS: *contrast with* [non-threshold effect](#)

threshold limit value

ACRONYM: TLV

- 1) Recommended guidelines for occupational exposure to airborne contaminants published by the American Conference of Governmental Industrial Hygienists (ACGIH). TLVs represent the average concentration in mg/m³ for an 8-hour workday and a 40-hour

workweek to which nearly all workers may be repeatedly exposed, day after day, without adverse effect. (EPA 2003)

- 2) Refers to airborne concentrations of substances and represents conditions under which it is believed that nearly all workers are protected while repeatedly exposed for an 8-hr day, 5 days a week (expressed as parts per million (ppm) for gases and vapors and as milligrams per cubic meter (mg/m^3) for fumes, mists, and dusts). (RAIS 2004, SRA 2004)

5.9 MODELING, STATISTICS, AND MATH TERMS

accuracy

- 1) The measure of the correctness of data, as given by the difference between the measured value and the true or standard value. (EPA 1997a, EPA 2004)
- 2) Degree of agreement between average predictions of a model or the average of measurements and the true value of the quantity being predicted or measured. (FAO/WHO 2003b)
- 3) The degree to which a measurement (e.g., the mean estimate of a treatment effect) is true or correct. An estimate can be accurate, yet not be precise, if it is based upon an unbiased method that provides observations having great variation (i.e., not close in magnitude to each other). (NLM/NICHRS 2004)
- 4) The degree of agreement between a measured value and the true value; usually expressed as +/- percent of full scale. (RAIS 2004, SRA 2004)

RELATED TERMS: *contrast with* [precision](#)

Akaikes information criterion

ACRONYM: AIC

These are criteria that are used in model selection to select the best model from a set of plausible models. One model is better than another model if it has a smaller AIC (or Bayesian information criterion (BIC)) value. AIC is based on Kullback-Leibler distance in information theory, and BIC is based on integrated likelihood in Bayesian theory. If the complexity of the true model does not increase with the size of the data set, BIC is the preferred criterion, otherwise, AIC is preferred. (Burnham and Anderson 1998)

RELATED TERMS: [Bayesian information criterion](#)

aleatory uncertainty

Aleatory is of or pertaining to natural or accidental causes and cannot be explained with mechanistic theory. Generally interpreted to be the same as stochastic variability. (FAO/WHO 2003b)

algorithm

- 1) A logical, step-by-step procedure used to solve problems in mathematics and computer programming. (AAS 1999)
- 2) A process or set of rules by which a calculation or process can be carried out usually referring to calculations that will be done by a computer. (CancerWEB 2005)
- 3) A computable set of steps to achieve a desired result. (NIST 2005)
- 4) A specific set of instructions for carrying out a procedure or solving a problem, usually with the requirement that the procedure terminate at some point. Specific algorithms sometimes also go by the name method, procedure, or technique. (Weisstein/MathWorld 2002)

analysis of variance

A statistical technique that isolates and assesses the contribution of categorical factors to variation in the mean of a continuous outcome variable. The data are divided into categories

based on their values for each of the independent variables, and the differences between the mean outcome values of these categories are tested for statistical significance. (Last 1983)

Anderson-Darling goodness of fit test

The Anderson-Darling test is used to test if a sample of data came from a population with a specific distribution. It is a modification of the Kolmogorov-Smirnov (K-S) test and gives more weight to the tails than does the K-S test. The K-S test is distribution free in the sense that the critical values do not depend on the specific distribution being tested. The Anderson-Darling test makes use of the specific distribution in calculating critical values. This has the advantage of allowing a more sensitive test and the disadvantage that critical values must be calculated for each distribution. The Anderson-Darling test is also an alternative to the chi-squared goodness-of-fit test. (NIST/SEMATECH 2005a)

RELATED TERMS: [Kolmogorov-Smirnov test](#)

approximation

An approach to a correct estimate, calculation, or conception, or to a given quantity, quality, etc; a continual approach or coming nearer to a result; as, to solve an equation by approximation. A value that is nearly but not exactly correct. (CancerWEB 2005)

arithmetic mean

- 1) The sum of all the measurements in a data set divided by the number of measurements in the data set. (EPA 1992)
- 2) A measure of central tendency. It is computed by adding all the individual values together and dividing by the number in the group. (Last 1983)

association

Statistical relationship between two or more events, characteristics, or other variables. (CDC 2005)

Bayes' theorem

A result that allows new information to be used to update the conditional probability of an event. (STEPS 1997)

Bayesian inference

Inference is using data to learn about some uncertain quantity. Bayes' theorem describes how to update a prior distribution about the uncertain quantity using a model (expressing likelihood of observed data) to obtain a posterior distribution. Bayesian inference allows incorporation of prior beliefs and can handle problems with insufficient data for frequentist inference. (FAO/WHO 2003b)

Bayesian information criterion

ACRONYM: BIC

SEE: [Akaike's information criterion](#)

Bayesian methods

These are an approach—founded on Bayes' theorem—that forms one of the two flows of statistics. Bayesian inference is very strong when only subjective data are available and is useful for using data to improve one's estimate of a parameter. (FAO/WHO 2003b)

Bernoulli distribution

SEE: [binomial distribution](#)

Bernoulli trial

A single random event for which there are two and only two possible outcomes that are mutually exclusive and have a priori fixed (and complementary) probabilities of resulting. The trial is the realization of this process. Conventionally one outcome is termed a success and is assigned the score 1, the other is a failure and has the score zero. (CancerWEB 2005)

RELATED TERMS: [binomial distribution](#)

best case

The situation or input for which an algorithm or data structure takes the least time or resources. (NIST 2005)

beta distribution

The general formula for the probability density function of the beta distribution is

$$f(x) = \frac{(x-a)^{p-1}(b-x)^{q-1}}{B(p,q)(b-a)^{p+q-1}} \quad a \leq x \leq b; p, q > 0$$

where p and q are the shape parameters, a and b are the lower and upper bounds, respectively, of the distribution, and $B(p,q)$ is the beta function. (NIST/SEMATECH 2005a)

beta error

- 1) The probability of a type II (false-negative) error. In hypothesis testing, β is the probability of concluding incorrectly that an intervention is not effective when it has true effect. $(1-\beta)$ is the power to detect an effect of an intervention if one truly exists. (NLM/NICHSR 2004)
- 2) In a hypothesis test, a beta (or type II) error occurs when the null hypothesis, H_0 , is not rejected when it is in fact false. For example, in a clinical trial of a new drug, the null hypothesis might be that the new drug is no better, on average, than the current drug; i.e., H_0 : there is no difference between the two drugs on average. A type II error would occur if it was concluded that the two drugs produced the same effect, i.e., there is no difference between the two drugs on average, when in fact they produced different ones. A type II error is frequently due to sample sizes being too small. The probability of a type II error is generally unknown, but is symbolised by β and written $P(\text{Type II error}) = \beta$. A type II error can also be referred to as an error of the second kind. (STEPS 1997)

RELATED TERMS: [null hypothesis](#), [power](#), [type II error](#)

bias

- 1) Systematic error introduced into sampling or analysis by selecting or encouraging one

- outcome or answer over others. (EPA 2004)
- 2) A set of standard criteria for deciding whether a person has a particular disease or health-related condition, by specifying clinical criteria and limitations on time, place, and person. (CDC 2005)
 - 3) A term that refers to how far the average statistic lies from the parameter it is estimating, that is, the error that arises when estimating a quantity. It is also referred to as “systematic error.” It is the difference between the mean of a model prediction or of a set of measurements and the true value of the quantity being predicted or measured. (FAO/WHO 2003b)
 - 4) In general, any factor that distorts the true nature of an event or observation. In clinical investigations, a bias is any systematic factor other than the intervention of interest that affects the magnitude of (i.e., tends to increase or decrease) an observed difference in the outcomes of a treatment group and a control group. Bias diminishes the accuracy (though not necessarily the precision) of an observation. Randomization is a technique used to decrease this form of bias. Bias also refers to a prejudiced or partial viewpoint that would affect someone’s interpretation of a problem. Double blinding is a technique used to decrease this type of bias. (NLM/NICHSR 2004)
 - 5) A systematic error arising from faulty study design, data collection, analysis, interpretation, etc. (NZ 2002)
 - 6) Any difference between the true value and that actually obtained due to all causes other than sampling variability. (RAIS 2004, SRA 2004)
 - 7) Bias is a term that refers to how far the average statistic lies from the parameter it is estimating, that is, the error which arises when estimating a quantity. Errors from chance will cancel each other out in the long run, those from bias will not. (STEPS 1997)

RELATED TERMS: [parameter](#)

binomial distribution

- 1) The probability distribution associated with two mutually exclusive outcomes; used to model cumulative incidence rates and prevalence rates. The Bernoulli distribution is a special case of binomial distribution. (CancerWEB 2005)
- 2) The binomial distribution is used when there are exactly two mutually exclusive outcomes of a trial. These outcomes are appropriately labeled “success” and “failure.” The binomial distribution is used to obtain the probability of observing x successes in N trials, with the probability of success on a single trial denoted by p . The binomial distribution assumes that p is fixed for all trials. The formula for the binomial probability mass function is

$$P(x, p, n) = \binom{n}{x} (p)^x (1 - p)^{(n-x)} \quad \text{for } x = 0, 1, 2, \dots, n$$

where

$$\binom{n}{x} = \frac{n!}{x!(n-x)!}$$

The binomial distribution is probably the most commonly used discrete distribution.

(NIST/SEMATECH 2005a)

- 3) An important theoretical distribution used to model discrete events, especially the count of defectives. The binomial distribution depends on two parameters, n and p . N is the total number of trials; for each trial, the chance of observing the event of interest is p , and of not observing it, $1-p$. The binomial distribution assumes each trial's outcome is independent of that of any other trial, and models the sum of events observed. Unlike the Poisson distribution, the binomial distribution sets a maximum number of events n , the sample size that can be observed. Unlike the hypergeometric distribution, the binomial distribution assumes the events it counts are independent. (NIST/SEMATECH 2005b)

RELATED TERMS: [Poisson distribution](#), [hypergeometric distribution](#)

bootstrap

A numerical method—also referred to as Bootstrap simulation—for inferring sampling distributions and confidence intervals for statistics of random variables. The methodology to estimate uncertainty involves generating subsets of the data on the basis of random sampling with replacements as the data are sampled. Such re-sampling means that each datum is equally represented in the randomization scheme (statistics). (Marsh 1996)

bounding estimate

- 1) An estimate of exposure, dose, or risk that is higher than that incurred by the person in the population with the currently highest exposure, dose, or risk. Bounding estimates are useful in developing statements that exposures, doses, or risks are not greater than an estimated value. (EPA 2005b)
- 2) An estimate of exposure, dose, or risk that is higher than that incurred by the person with the highest exposure, dose, or risk in the population being assessed. Bounding estimates are useful in developing statements that exposures, doses, or risks are “not greater than” the estimated value. (IPCS 2004)

chi-squared distribution

- 1) A distribution in which a variable is distributed like the sum of the squares of any given independent random variable, each of which has a normal distribution with mean of zero and variance of one. (CancerWEB 2005)
- 2) The chi-square distribution results when ν independent variables with standard normal distributions are squared and summed. The formula for the probability density function of the chi-square distribution is

$$f(x) = \frac{e^{-x/2} x^{v/2-1}}{2^{v/2} \Gamma(v/2)} \quad \text{for } x \geq 0$$

Where ν is the shape parameter and Γ is the gamma function. The formula for the gamma function is

$$\Gamma(a) = \int_0^{\infty} t^{a-1} e^{-t} dt$$

In a testing context, the chi-square distribution is treated as a “standardized distribution” (i.e., no location or scale parameters). However, in a distributional modeling context (as

with other probability distributions), the chi-square distribution itself can be transformed with a location parameter, μ , and a scale parameter, σ . (NIST/SEMATECH 2005a)
Also called “chi-square” distribution, even though “chi-squared” is technically correct.

chi-squared goodness-of-fit test

- 1) The chi-square test is used to test if a sample of data came from a population with a specific distribution. An attractive feature of the chi-square goodness-of-fit test is that it can be applied to any univariate distribution for which you can calculate the cumulative distribution function. The chi-square goodness-of-fit test is applied to binned data (i.e., data put into classes). This is actually not a restriction since for non-binned data one can simply calculate a histogram or frequency table before generating the chi-square test. However, the value of the chi-square test statistic is dependent on how the data is binned. Another disadvantage of the chi-square test is that it requires a sufficient sample size in order for the chi-square approximation to be valid. (NIST/SEMATECH 2005a)
- 2) The chi-squared goodness of fit test is a test for comparing a theoretical distribution, such as a Normal, Poisson etc, with the observed data from a sample. (STEPS 1997)

cluster analysis

A set of statistical methods used to group variables or observations into strongly inter-related subgroups. In epidemiology, it may be used to analyze a closely grouped series of events or cases of disease or other health-related phenomenon with well-defined distribution patterns in relation to time or place or both. (CancerWEB 2005)

coefficient of variation**ACRONYM:** CV

- 1) A dimensionless measure of dispersion, equal to the standard deviation divided by the mean, often expressed as a percentage. (EPA 2004)
- 2) The ratio of the standard deviation to the mean. This is meaningful only if the variable is measured on a ratio scale. (Last 1983)

confidence interval

- 1) A range of values that has a specified probability (e.g., 95 percent) of containing the statistical parameter (i.e., a quantity such as a mean or variance that describes a statistical population) in question. The confidence limit refers to the upper or lower value of the range. (EPA 2004)
- 2) A range of values for a variable of interest, e.g., a rate, constructed so that this range has a specified probability of including the true value of the variable. The specified probability is called the confidence level, and the end points of the confidence interval are called the confidence limits. (CDC 2005)
- 3) A range of values inferred or believed to enclose the actual or true value of an uncertain quantity with a specified degree of probability. Confidence intervals may be inferred based upon sampling distributions for a statistic. (FAO/WHO 2003b)
- 4) Depicts the range of uncertainty about an estimate of a treatment effect. It is calculated from the observed differences in outcomes of the treatment and control groups and the sample size of a study. The confidence interval (CI) is the range of values above and

below the point estimate that is likely to include the true value of the treatment effect. The use of CIs assumes that a study provides one sample of observations out of many possible samples that would be derived if the study were repeated many times. Investigators typically use CIs of 90%, 95%, or 99%. For instance, a 95% CI indicates that there is a 95% probability that the CI calculated from a particular study includes the true value of a treatment effect. If the interval includes a null treatment effect (usually 0.0, but 1.0 if the treatment effect is calculated as an odds ratio or relative risk), the null hypothesis of no true treatment effect cannot be rejected. (NLM/NICHSR 2004)

- 5) (95%) Under the assumption of a given statistical model, the range of values for an estimated statistic constructed so that under repeated sampling its true value will lie within such intervals for 95% of the time. For a particular interval one cannot say with 95% confidence that the true value lies within the interval—unless one adopts a Bayesian approach, in which case a particular prior distribution will have been (probably unwittingly) adopted. This is then called a credibility interval. Confidence and credibility intervals usually have the same numerical limits if the prior distribution posits that all values are equally likely (and this may not be a tenable assumption). (NZ 2002)
- 6) A range of values ($a_1 < a < a_2$) determined from a sample of definite rules so chosen that, in repeated random samples from the hypothesized population, an arbitrarily fixed proportion of that range will include the true value, x , of an estimated parameter. The limits, a_1 and a_2 , are called confidence limits; the relative frequency with which these limits include a is called the confidence coefficient; and the complementary probability is called the confidence level. As with significance levels, confidence levels are commonly chosen as 0.05 or 0.01, the corresponding confidence coefficients being 0.95 or 0.99. Confidence intervals should not be interpreted as implying that the parameter itself has a range of values; it has only one value, a . On the other hand, the confidence limits (a_1 , a_2) being derived from a sample, are random variables, the values of which on a particular sample either do or do not include the true value a of the parameter. However, in repeated samples, a certain proportion of these intervals will include a provided that the actual population satisfied the initial hypothesis. (RAIS 2004, SRA 2004)
- 7) A confidence interval gives an estimated range of values that is likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data. If independent samples are taken repeatedly from the same population, and a confidence interval calculated for each sample, then a certain percentage (confidence level) of the intervals will include the unknown population parameter. Confidence intervals are usually calculated so that this percentage is 95%, but we can produce 90%, 99%, 99.9% (or whatever) confidence intervals for the unknown parameter. The width of the confidence interval gives us some idea about how uncertain we are about the unknown parameter (see precision). A very wide interval may indicate that more data should be collected before anything very definite can be said about the parameter. Confidence intervals are more informative than the simple results of hypothesis tests (where we decide “reject H_0 ” or “don’t reject H_0 ”) since they provide a range of plausible values for the unknown parameter. (STEPS 1997)

RELATED TERMS: [parameter](#)

contagious distribution

A probability distribution describing a stochastic process consisting of a combination of two or more processes. Also referred to as a “mixture distribution” (statistics). (FAO/WHO 2003b)

continuous time model

A model in which the system changes continuously over time. Derivatives (e.g., dY/dt) are the mathematical formalism for describing such continuous change. The differential equation which embodies a model provides the values of these derivatives at any particular time point; calculus or a computer can then be used to move the state of the model forwards in time. Continuous models have the advantage over discrete time models in that they are more amenable to algebraic manipulation, although they are slightly harder to implement on a computer. The same as a differential equation model. (Swinton 1999)

controllable variability

Sources of heterogeneity of values of time, space or different members of a population that can be modified in part—in principle, at least—by intervention, such as a control strategy. For example, variability in the time and temperature history of food storage among storage devices influences variability in pathogen growth among food servings and in principle could be modified through a control strategy. For both population and individual risk, controllable variability is a component of overall variability. (FAO/WHO 2003b)

correlation

Relationship that results when a change in one variable is consistently associated with a change in another one. (EDVCB 2000)

cumulative distribution function**ACRONYM:** CDF

- 1) Cumulative distribution functions are particularly useful for describing the likelihood that a variable will fall within different ranges of x . $F(x)$ (i.e., the value of y at x in a CDF plot) is the probability that a variable will have a value less than or equal to x . (EPA 1998a)
- 2) The CDF is alternatively referred to in the literature as the distribution function, cumulative frequency function, or the cumulative probability function. The cumulative distribution function, $F(x)$, expresses the probability the random variable X assumes a value less than or equal to some value x , $F(x) = \text{Prob}(X \leq x)$. For continuous random variables, the cumulative distribution function is obtained from the probability density function by integration, or by summation in the case of discrete random variables. (EPA 2004)
- 3) The risk of a common toxic effect associated with concurrent exposure by all relevant pathways and routes of exposure to a group of chemicals that share a common mechanism of toxicity. (EPA 2005e)
- 4) All random variables (discrete and continuous) have a cumulative distribution function. It is a function giving the probability that the random variable X is less than or equal to x , for every value x . Formally, the cumulative distribution function $F(x)$ is defined to be:

$$F(x) = P(X \leq x) \quad \text{for} \quad -\infty < x < \infty$$

For a discrete random variable, the cumulative distribution function is found by summing up the probabilities. For a continuous random variable, the cumulative distribution function is the integral of its probability density function. (STEPS 1997)

RELATED TERMS: [probability density function](#)

decision tree

- 1) A hierarchy of rules within a computer program, represented by a tree-like structure, that enables a set of data to be classified. A series of selection criteria classify the data into smaller and smaller categories. (AAS 1999)
- 2) Alternative choices available at each stage of deciding how to manage a clinical problem, displayed graphically; at each branch or decision node, the probabilities of each outcome that can be predicted are shown; the relative worth of each outcome is described in terms of its utility or quality of life, e.g., as measured by probability of life expectancy or freedom from disability. (CancerWEB 2005)

dependent variable

- 1) In experiments, a variable that is influenced by or dependent upon changes in the independent variable. (CancerWEB 2005)
- 2) In a statistical analysis, the outcome variable(s) or the variable(s) whose values are a function of other variable(s) (called independent variable(s) in the relationship under study). (CDC 2005)

RELATED TERMS: *contrast with* [independent variable](#)

deterministic

A methodology relying on point (i.e., exact) values as inputs to estimate risk; this obviates quantitative estimates of uncertainty and variability. Results are also presented as point values. Uncertainty and variability may be discussed qualitatively, or semi-quantitatively by multiple deterministic risk estimates. (EPA 2004)

deterministic analysis

Calculation and expression of health risks as single numerical values or “single point” estimates of risk. In risk assessments, the uncertainty and variability are discussed in a qualitative manner. (EPA 2005e)

deterministic model

A mathematical model in which the parameters and variables are not subject to random fluctuations, so that the system is at any time entirely defined by the initial conditions chosen. Contrast with a stochastic model. (Swinton 1999)

distribution

- 1) A set of values derived from a specific population or set of measurements that represents the range and array of data for the factor being studied. (EPA 1997a)
- 2) In epidemiology, the frequency and pattern of health-related characteristics and events in a population. In statistics, the observed or theoretical frequency of values of a variable. (CDC 2005)

- 3) A series of values or a mathematical equation describing a series of values. (FDA 2002)
- 4) The arrangement in space and time of a specific microorganism or disease caused by that microorganism. (ILSI 2000)
- 5) The complete summary of the frequencies of the values or categories of a measurement made on a group of persons. The distribution tells either how many or what proportion of the group were found to have each value (or each range of values) out of all the possible values that the quantitative measure can have. (Last 1983)
- 6) A representation of the frequency of occurrence of values of a variable, especially of a response. (NIST/SEMATECH 2005b)

RELATED TERMS: [sample](#), [sampling distribution](#)

distribution-free method

A method of testing a hypothesis or of setting up a confidence interval that does not depend on the form of the underlying distribution; in particular, it does not depend upon the variable following a normal distribution. (Last 1983)

dose-response, linear-quadratic

A linear-quadratic dose response is a relationship between dose and biological response that is curved. This implies that the rate of change in response is different at different doses. The response may change slowly at low doses, for example, but rapidly at high doses. A linear-quadratic dose response is written mathematically as follows: if Y represents the expected, or average response and D represents dose, then $Y = aD + bD^2$ where a is the linear coefficient (or slope) and b is the quadratic coefficient (or curvature). (RERF 1999).

dynamic model

Considers the individual within a community rather than the isolated individual. Time-dependent elements such as secondary transmission, host immunity, and animal reservoirs are included. (ILSI 2000 text)

empirical

Pertaining to, or founded upon, experiment or experience; depending upon the observation of phenomena; versed in experiments. (CancerWEB 2005)

empirical distribution

A representation of observed values or data of a series or population. (FDA 2002)

erlang distribution

SEE: [gamma distribution](#)

error

- 1) Any discrepancy between a computed, observed, or measured quantity and the true, specified, or theoretically correct value of that quantity. (1) random error – in statistics, an error that can be predicted only on a statistical basis; (2) systematic error – in statistics, an error which results from some bias in the measurement process and is not due to chance, in contrast to random error. (AIHA 2000)

- 2) A false or mistaken result obtained in a study or experiment. Several kinds of error can occur in epidemiology, for example, due to bias:
 - Random error (sampling error) is that due to chance, when the result obtained in the sample differs from the result that would be obtained if the entire population (“niverse”) were studied. Two varieties of sampling error are type I, or alpha error, and type II, or beta error. In an experiment, if the experimental procedure does not in reality have any effect, an apparent difference between experimental and control groups may nevertheless be observed by chance, a phenomenon known as type I error. Another possibility is that the treatment is effective but by chance the difference is not detected on statistical analysis—type II error. In the theory of testing hypotheses, rejecting a null hypothesis when it is actually true is called “type I error.” Accepting a null hypothesis when it is incorrect is called “type II error.”
 - Systematic error is that due to factors other than chance, such as faulty measuring instruments. It is further considered in bias. (Last 1983)

extrapolation

- 1) In risk assessment, this process entails postulating a biologic reality based on observable responses and developing a mathematical model to describe this reality. The model may then be used to extrapolate to response levels that cannot be directly observed. (MERREA 2005, RAIS 2004, SRA 2004)
- 2) Extrapolation is when the value of a variable is estimated at times which have not yet been observed. This estimate may be reasonably reliable for short times into the future, but for longer times, the estimate is liable to become less accurate. (STEPS 1997)

fate and transport modeling

The mathematical equations simulating a physical system which are used to assess and predict the movement and behavior of chemicals in the environment. (EPA 2004)

fault tree

A method of analyzing potential outcomes which starts with the final event and works backwards, identifying all causes of the event, the contributing factors of those causes, etc., back to the basic events. Probabilities can be assigned to the basic events, and a likelihood thus estimated for the final event. (AIHA 2000)

fault tree analysis

A technique by which many events that interact to produce other events can be related using simple logical relationships permitting a methodical building of a structure that represents the system. (SRA 2004)

frequency distribution

- 1) A distribution describing the rate or frequency of occurrence of a value in a series or population arranged in ascending or descending order. (FDA 2002)
- 2) A complete summary of the frequencies of the values or categories of a variable; often displayed in a two column table: the left column lists the individual values or categories,

the right column indicates the number of observations in each category. (CDC 2005)

gamma distribution

The general formula for the probability density function of the gamma distribution is

$$f(x) = \frac{\left(\frac{x-\mu}{\beta}\right)^{\gamma-1} \exp\left(-\frac{x-\mu}{\beta}\right)}{\beta \Gamma(\gamma)} \quad x \geq \mu; \gamma, \beta > 0$$

Where γ is the shape parameter, μ is the location parameter, β is the scale parameter, and Γ is the gamma function which has the formula

$$\Gamma(a) = \int_0^{\infty} t^{a-1} e^{-t} dt$$

The case where $\mu = 0$ and $\beta = 1$ is called the standard gamma distribution. The equation for the standard gamma distribution reduces to

$$f(x) = \frac{x^{\gamma-1} e^{-x}}{\Gamma(\gamma)} \quad x \geq 0; \gamma > 0$$

The gamma is a flexible life distribution model that may offer a good fit to some sets of failure data. It is not, however, widely used as a life distribution model for common failure mechanisms. A common use of the gamma model occurs in Bayesian reliability applications. (NIST/SEMATECH 2005a)

Gaussian distribution

SEE: [normal distribution](#)

Gaussian distribution model

A commonly used assumption about the distribution of values for a parameter, also called the normal distribution. For example, a Gaussian air dispersion model is one in which the pollutant is assumed to spread in air according to such a distribution and described by two parameters, the mean and standard deviation of the normal distribution. (MERREA 2005, RAIS 2004, SRA 2004)

RELATED TERMS: [normal distribution](#)

geometric distribution

Geometric distributions model (some) discrete random variables. Typically, a geometric random variable is the number of trials required to obtain the first failure, for example, the number of tosses of a coin until the first “tail” is obtained, or a process where components from a production line are tested, in turn, until the first defective item is found. A discrete random variable X is said to follow a geometric distribution with parameter p , written $X \sim \text{Ge}(p)$, if it has probability distribution

$$P(X=x) = p^{x-1}(1-p)$$

where

$$x = 1, 2, 3, \dots$$

$$p = \text{success probability}; 0 < p < 1$$

The trials must meet the following requirements:

- a. the total number of trials is potentially infinite;
- b. there are just two outcomes of each trial; success and failure;
- c. the outcomes of all the trials are statistically independent;
- d. all the trials have the same probability of success.

The geometric distribution has expected value $E(X) = 1/(1-p)$ and variance $V(X) = p/\{(1-p)^2\}$. The geometric distribution is related to the binomial distribution in that both are based on independent trials in which the probability of success is constant and equal to p . However, a geometric random variable is the number of trials until the first failure, whereas a binomial random variable is the number of successes in n trials. (STEPS 1997)

geometric mean

- 1) The n^{th} root of the product of n values. (EPA 1997a)
- 2) A measure of central tendency. Calculable only for positive values. It is calculated by taking the logarithms of the values, calculating their arithmetic mean, then converting back by taking the antilogarithm. (Last 1983)

goodness of fit

Degree of agreement between an empirically observed distribution and a mathematical or theoretical distribution. (CancerWEB 2005)

goodness-of-fit test

A procedure for critiquing and evaluating the potential inadequacies of a probability distribution model with respect to its fitness to represent a particular set of observations. (FAO/WHO 2003b)

histogram

- 1) A graphic columnar or bar representation to compare the magnitudes of frequencies or numbers of items; graphical representation of the frequency distribution of a variable, in which rectangles are drawn with their bases on a uniform linear scale representing intervals, and their heights are proportional to the values within each of the intervals. (CancerWEB 2005)
- 2) A graphic representation of the frequency distribution of a continuous variable. Rectangles are drawn in such a way that their bases lie on a linear scale representing different intervals, and their heights are proportional to the frequencies of the values within each of the intervals. (CDC 2005)
- 3) The purpose of a histogram is to graphically summarize the distribution of a univariate data set. The histogram graphically shows the following:
 - (a) center (i.e., the location) of the data;
 - (b) spread (i.e., the scale) of the data;
 - (c) skewness of the data;
 - (d) presence of outliers; and
 - (e) presence of multiple modes in the data.

These features provide strong indications of the proper distributional model for the data. The probability plot or a goodness-of-fit test can be used to verify the distributional

model. (NIST/SEMATECH 2005a)

- 4) A graphical display of a statistical distribution; a form of bar chart. One axis (usually x) is the scale of the values observed, the second (usually y) is the frequency that observations occur with (approximately) that value. (NIST/SEMATEC 2005b)
- 5) A histogram is a way of summarizing data that are measured on an interval scale (either discrete or continuous). It is often used in exploratory data analysis to illustrate the major features of the distribution of the data in a convenient form. It divides up the range of possible values in a data set into classes or groups. For each group, a rectangle is constructed with a base length equal to the range of values in that specific group, and an area proportional to the number of observations falling into that group. This means that the rectangles might be drawn of non-uniform height. The histogram is only appropriate for variables whose values are numerical and measured on an interval scale. It is generally used when dealing with large data sets (>100 observations), when stem and leaf plots become tedious to construct. A histogram can also help detect any unusual observations (outliers), or any gaps in the data set. (STEPS 1997)

hypergeometric distribution

An important distribution used to model discrete events, especially the count of defectives when sampling without replacement. The hypergeometric distribution depends on three parameters, N , n , and D . N is the known and finite population size, n the known sample size (constrained to be less than or equal to N), and D , the unknown number of defectives. Unlike the binomial distribution, the hypergeometric distribution assumes sampling is without replacement, and that its parameters are all integer-valued. (NIST/SEMATECH 2005b)

RELATED TERMS: [binomial distribution](#)

independent variable

- 1) A characteristic being measured or observed that is hypothesised to influence another event or manifestation (the dependent variable) within a defined area of relationships under study; that is, the independent variable is not influenced by the event or manifestation, but may cause it or contribute to its variation. (CancerWEB 2005)
- 2) An exposure, risk factor, or other characteristic being observed or measured that is hypothesized to influence an event or manifestation (the dependent variable). (CDC 2005)

RELATED TERMS: *contrast with* [dependent variable](#)

iteration

One computational cycle of a set of instructions (e.g., formula, algorithm) that is repeated a specified number of times. (FDA 2002)

Kolmogorov-Smirnov test

ACRONYM: K-S test

- 1) The Kolmogorov-Smirnov (K-S) test is used to decide if a sample comes from a population with a specific distribution. An attractive feature of this test is that the distribution of the K-S test statistic itself does not depend on the underlying cumulative distribution function being tested. Another advantage is that it is an exact test (the chi-

square goodness-of-fit test depends on an adequate sample size for the approximations to be valid). Despite these advantages, the K-S test has several important limitations: (1) it only applies to continuous distributions, (2) it tends to be more sensitive near the center of the distribution than at the tails, and (3) perhaps the most serious limitation is that the distribution must be fully specified; that is, if location, scale, and shape parameters are estimated from the data, the critical region of the K-S test is no longer valid. It typically must be determined by simulation. Due to limitations 2 and 3 above, many analysts prefer to use the Anderson-Darling goodness-of-fit test. (NIST/SEMATECH 2005a)

- 2) For a single sample of data, the Kolmogorov-Smirnov test is used to test whether or not the sample of data is consistent with a specified distribution function. When there are two samples of data, it is used to test whether or not these two samples may reasonably be assumed to come from the same distribution. The Kolmogorov-Smirnov test does not require the assumption that the population is normally distributed. (STEPS 1997)

RELATED TERMS: [Anderson-Darling goodness-of-fit test](#)

likelihood

The probability of the observed data for various values of the unknown model parameters (statistics). (Last 1995)

linear correlation coefficient

A measure of the tendency for there to be a linear relationship between (X, Y) pairs of data. Measured by Pearson's coefficient (r), usually just called "correlation coefficient" (so the unwary may not realize that it measures only a linear relationship). (NZ 2002)

RELATED TERMS: [rank correlation coefficient](#)

linear dose response

- 1) A pattern of frequency or severity of biological response that varies directly with the amount of dose of an agent. (EPA 2003)
- 2) A linear dose response is a relationship between dose and biological response that is a straight line. In other words, the rate of change (slope) in the response is the same at any dose. A linear dose response is written mathematically as follows: if Y represents the expected, or average response and D represents dose, then $Y = aD$ where a is the slope, also called the linear coefficient. (RERF 1999)

linear model

- 1) Statistical models in which the value of a parameter for a given value of a factor is assumed to be equal to $a + bx$, where a and b are constants. The models predict a linear regression. (CancerWEB 2005)
- 2) A statistical model of a dependent variable y as a function of a factor, x: $y = a + bx + E$, where E represents random variation. (Last 1983)

lognormal distribution

- 1) If a variable y is such that $x = \log y$, it is said to have a lognormal distribution; this is a skew distribution. (CancerWEB 2005)

- 2) If a variable Y is such that $X = \log Y$ is normally distributed, it is said to have lognormal distribution. This is a skew distribution. (Last 1983)
- 3) A variable X is lognormally distributed if $Y = \text{LN}(X)$ is normally distributed with “LN” denoting the natural logarithm. The general formula for the probability density function of the lognormal distribution is

$$f(x) = \frac{e^{-((\ln((x-\theta)/m))^2/(2\sigma^2))}}{(x-\theta)\sigma\sqrt{2\pi}} \quad x \geq \theta; m, \sigma > 0$$

where σ is the shape parameter, θ is the location parameter and m is the scale parameter. The case where $\theta = 0$ and $m = 1$ is called the standard lognormal distribution. The case where θ equals zero is called the 2-parameter lognormal distribution. The equation for the standard lognormal distribution is

$$f(x) = \frac{e^{-((\ln x)^2/2\sigma^2)}}{x\sigma\sqrt{2\pi}} \quad x \geq 0; \sigma > 0$$

(NIST/SEMATECH 2005a)

log-probit model

A dose-response model which assumes that each animal has its own threshold dose, below which no response occurs and above which a tumor [or other effect] is produced by exposure to a chemical. (MERREA 2005, RAIS 2004, SRA 2004)

logistic distribution

The continuous distribution with parameters m and $b > 0$ having probability and distribution functions:

$$P(x) = \frac{e^{-(x-m)/b}}{b[1 + e^{-(x-m)/b}]^2} \quad (1)$$

$$D(x) = \frac{1}{1 + e^{-(x-m)/b}} \quad (2)$$

The distribution function is similar in form to the solution to the continuous logistic equation giving the distribution its name. (Weisstein/MathWorld 2003)

logistic model

A dose-response model used for low-dose extrapolation, of the form:

$$P(d) = \gamma + \frac{1-\gamma}{1 + e^{-(\alpha + \beta d)}}$$

where: $P(d)$ = probability of cancer from lifetime, continuous exposure at dose rate d , and
 α, β = fitted parameters; and
 γ = background incidence rate. (EPA 2003)

logit model

A dose-response model which, like the probit model, leads to an S-shaped dose-response curve, symmetrical about the 50% response point. The logit model leads to lower “very safe doses” than the probit model, even when both models are equally descriptive of the data in the observable range. (MERREA 2005, RAIS 2004, SRA 2004)

low-dose extrapolation

An estimation of the dose-response relationship at doses less than the lowest dose studied experimentally. (EPA 2004)

low-dose linear model

A low-dose-linear model is one whose slope is greater than zero at a dose of zero. A low-dose-linear model approximates a straight line only at very low doses; at higher doses near the observed data, a low-dose-linear model can display curvature. The term “low-dose-linear” is often abbreviated “linear,” although a low-dose-linear model is not linear at all doses. Use of nonlinear approaches does not imply a biological threshold dose below which the response is zero. Estimating thresholds can be problematic; for example, a response that is not statistically significant can be consistent with a small risk that falls below an experiment’s power of detection. (EPA 2005a)

Markov chain Monte Carlo

- 1) A general method of sampling arbitrary highly-dimensional probability distributions by taking a random walk through configuration space. One changes the state of the system randomly according to a fixed transition rule, thus generating a random walk through state space, s_0, s_1, s_2, \dots . The definition of a Markov process is that the next step is chosen from a probability distribution that depends only on the present position. This makes it very easy to describe mathematically. The process is often called the drunkard’s walk (statistics). (FAO/WHO 2003b)
- 2) A type of quantitative modeling that involves a specified set of mutually exclusive and exhaustive states (e.g., of a given health status), and for which there are transition probabilities of moving from one state to another (including of remaining in the same state). Typically, states have a uniform time period, and transition probabilities remain constant over time. (NLM/NICHSR 2004)

RELATED TERMS: [Monte-Carlo simulation](#)

mathematical modeling

A representation of aspects of the behavior of a system by creating an approximate (mathematical) description based on theory or phenomenon that accounts for its known or inferred properties. (FDA 2002)

maximum likelihood estimate

ACRONYM: MLE

Statistical method for estimating model parameters. Generally provides a mean or central tendency estimate, as opposed to a confidence limit on the estimate. (EPA 2003)

maximum likelihood method**ACRONYM:** ML method**SEE:** [maximum likelihood estimate](#)**mean**

- 1) mean, arithmetic: The sum of numbers divided by the number of numbers. (NZ 2002)
- 2) mean, geometric: The nth root of the product of n numbers; the same as the antilog of the mean of the logarithms. Tends to be a better measure of central tendency for skewed distributions, but is zero if any datum is zero. Estimates the geometric mean of a lognormal distribution, but with some bias (which can be corrected). (NZ 2002)

measures of central tendency

A general term for several characteristics of the distribution of a set of values or measurements around a value or values at or near the middle of the set. The principal measures of central tendency are the mean (average), median, and mode. (Last 1983)

median

- 1) The middle value in a population distribution, above and below which lie an equal number of individual values; midpoint. (CARB 2000)
- 2) A measure of central tendency. The simplest division of a set of measurements is into two parts—the lower and the upper half. The point on the scale that divides the group in this way is called the “median.” (Last 1983)
- 3) The midpoint value obtained by ranking all values from highest to lowest and choosing the value in the middle. The median divides a population into two equal halves. (NIAID 2000)
- 4) The middle value of n numbers (if n is even it is the arithmetic mean of the middle two numbers). (NZ 2002)

median dose**ACRONYM:** N₅₀

This value is a parameter used in microbial dose-response models (e.g., exponential and Poisson) and has been used in microbial risk assessment to determine the probability of infection. (EPA 2005f)

meta-analysis

- 1) A family of statistical methods that quantitatively combine the results of separate investigations into a single statement of overall significance. (NIST/SEMATECH 2005b)
- 2) Systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. (NLM/NICHSR 2004)

RELATED TERMS: [systematic review](#)

metamodel calibration

The practice of determining unknown parameters of a model by the following steps:

- (a) Run a computer experiment by varying the unknown parameters, and recording the expected responses.
- (b) Fit a model of general form, especially a neural network, using the responses of the computer experiment as inputs and the factors as the outputs.
- (c) Extract the unknown parameters as the outputs that result from this model when the inputs are taken to be the empirically observed values. (NIST/SEMATECH 2005b)

mode

- 1) The value in the data set that occurs most frequently. (EPA 1992)
- 2) One of the measures of central tendency. The most frequently occurring value in a set of observations. (Last 1983)

model

- 1) A mathematical function with parameters that can be adjusted so the function closely describes a set of empirical data. A mechanistic model usually reflects observed or hypothesized biological or physical mechanisms, and has model parameters with real world interpretation. In contrast, statistical or empirical models selected for particular numerical properties are fitted to data; model parameters may or may not have real world interpretation. When data quality is otherwise equivalent, extrapolation from mechanistic models (e.g., biologically based dose-response models) often carries higher confidence than extrapolation using empirical models (e.g., logistic model). (EPA 2003)
- 2) A mathematical representation of a natural system intended to mimic the behavior of the real system, allowing description of empirical data, and predictions about untested states of the system. (EPA 2004)
- 3) A set of constraints restricting the possible joint values of several quantities. A hypothesis or system of belief regarding how a system works or responds to changes in its inputs. The purpose of a model is to represent a particular system of interest as accurately and precisely as necessary with respect to particular decision objectives. (FAO/WHO 2003b)
- 4) A representation of something, often idealized or modified to make it conceptually easier to understand. (CancerWeb 2005)
- 5) A framework for thinking and acting. (MERREA 2005)
- 6) A mathematical statement of the relation(s) among variables. Models can be of two basic types, or have two basic parts: statistical models, which predict a measured quantity; probability models, which predict the relative frequency of different random outcomes. (NIST/SEMATECH 2005b)

model boundaries

Designated areas of competence of the model, including time, space, pathogens, pathways and exposed populations, and acceptable ranges of values for each input and jointly among all inputs for which the model meets data quality objectives. (FAO/WHO 2003b)

model detail

Level of simplicity or detail associated with the functional relationships assumed in the model compared to the actual but unknown relationships in the system being modeled. (FAO/WHO 2003b)

model structure

A set of assumptions and inference options upon which a model is based, including underlying theory as well as specific functional relationships. (FAO/WHO 2003b)

model uncertainty

- 1) Uncertainty due to necessary simplification of real-world processes, misspecification of the model structure, model misuse, or use of inappropriate surrogate variables or inputs. (EPA 2004)
- 2) Bias or imprecision associated with compromises made or lack of adequate knowledge in specifying the structure and calibration (parameter estimation) of a model. (FAO/WHO 2003b)

model validation

The process by which the model is evaluated by comparing a model prediction with empirical data. (FDA 2002)

modeling

An investigative technique using a mathematical or physical representation of a system or theory that accounts for all or some of its known properties. (EPA 2004)

modeling node

In air quality modeling, the location where impacts are predicted. (EPA 2004)

modifying factor**ACRONYM: MF**

A factor used in the derivation of a reference dose or reference concentration. The magnitude of the MF reflects the scientific uncertainties of the study and database not explicitly treated with standard uncertainty factors (e.g., the completeness of the overall database). A MF is greater than zero and less than or equal to 10, and the default value for the MF is 1. (EPA 2003)

Monte-Carlo analysis

A statistical technique which uses random numbers to determine whether a set of data values is random. A Monte-Carlo analysis simulates situations where elements of risk are affected by variations in the value of a variable to determine which of these variations have the greatest influence on the various elements of risk. This technique also can be used for comparing alternatives involving elements of risk or alternative economic decisions. (NYS 1998)

Monte-Carlo sampling

A computer experimental method that uses random numbers in order to estimate distributions of simulator outputs. (NIST/SEMATECH 2005b)

Monte-Carlo simulation

- 1) A process for making repeated calculations with minor variations of the same mathematical equation, usually with the use of a computer. May be used to integrate variability in the predicted results for a population or the uncertainty of a predicted result. A two-dimensional Monte Carlo simulation may be used to do both. (FDA 2002)
- 2) A technique used in computer simulations that uses sampling from a random number sequence to simulate characteristics or events or outcomes with multiple possible values. For example, this can be used to represent or model many individual patients in a population with ranges of values for certain health characteristics or outcomes. In some cases, the random components are added to the values of a known input variable for the purpose of determining the effects of fluctuations of this variable on the values of the output variable. (NLM/NICHSR 2004)
- 3) A technique that can provide a probability function of estimated exposure using distributed values of exposure factors in an exposure scenario. The Monte Carlo simulation involves assigning a joint probability distribution to the input variables (i.e., exposure factors) of an exposure scenario. Next, a large number of independent samples from the assigned joint distribution are taken and the corresponding outputs calculated. This is accomplished by repeated computer runs (i.e., $\geq 1,000$ iterations), using random numbers to assign values to the exposure factors. The simulated output represents a sample from the true output distribution. Methods of statistical inference are used to estimate, from the exposure output sample, some parameters of the exposure distribution, such as percentiles, mean, variance, and confidence intervals. The Monte Carlo simulation can also be used to test the effect that an input parameter has on the output distribution. (REAP 1995)

RELATED TERMS: [Markov chain MonteCarlo](#)

Monte Carlo technique

- 1) A repeated random sampling from the distribution of values for each of the parameters in a generic (exposure or dose) equation to derive an estimate of the distribution of (exposures or doses in) the population. (EPA 1997a)
- 2) A repeated random sampling from the distribution of values for each of the parameters in a calculation (e.g., lifetime average daily exposure), to derive a distribution of estimates (of exposures) in the population. (EPA 2003)
- 3) A repeated random sampling from the distribution of values for each of the parameters in a generic exposure or risk equation to derive an estimate of the distribution of exposures or risks in the population. (EPA 2004)

multiple regression

Multiple linear regression aims to find a linear relationship between a response variable and several possible predictor variables. (STEPS 1997)

RELATED TERMS: [regression analysis](#)

multistage model

- 1) A mathematical function used to extrapolate the probability of cancer from animal

bioassay data, using the form:

$$P(d) = 1 - e^{-(q_0 + q_1 d + q_2 d^2 + \dots + q_k d^k)}$$

where:

$P(d)$ = probability of cancer from a continuous, lifetime exposure rate d ;

q_i = fitted dose coefficients of model; $i = 0, 1, \dots, k$; and

k = number of stages selected through best fit of the model, no greater than one less than the number of available dose groups. (EPA 2003, EPA 2004)

- 2) A carcinogenesis dose-response model where it is assumed that cancer originates as a “malignant” cell, which is initiated by a series of somatic-like mutations occurring in finite steps. It is also assumed that each mutational stage can be depicted as a Poisson process in which the transition rate is approximately linear in dose rate. (RAIS 2004, SRA 2004)

multistage Weibull model

A dose-response model for low-dose extrapolation which includes a term for decreased survival time associated with tumor incidence:

$$P(d, t) = 1 - e^{-(q_0 + q_1 d + q_2 d^2 + \dots + q_k d^k)(t - t_0)^z}$$

where:

$P(d, t)$ = the probability of a tumor (or other response) from lifetime, continuous exposure at dose d until age t (when tumor is fatal);

q_i = fitted dose parameters, $i=0, 1, \dots, k$;

k = no greater than the number of dose groups - 1;

t_0 = the time between when a potentially fatal tumor becomes observable and when it causes death ($t_0^3 1$); and

z = fitted time parameter (also called “Weibull” parameter).

(EPA 2003, EPA 2004)

normal distribution

- 1) A distribution of data points with most values close to the center or norm, and fewer and fewer occurring as we move further and further out from the norm. If a particular data set closely fits a normal distribution curve, the implication is that nothing is going on in that situation except random variation around a norm. (Brooks 2001)
- 2) Continuous frequency distribution of infinite range. Its properties are as follows: (1) continuous, symmetrical distribution with both tails extending to infinity; (2) arithmetic mean, mode, and median identical; and (3) shape completely determined by the mean and standard deviation. (CancerWEB 2005)
- 3) The symmetrical clustering of values around a central location. The properties of a normal distribution include the following: (1) It is a continuous, symmetrical distribution; both tails extend to infinity; (2) the arithmetic mean, mode, and median are identical;

and, (3) its shape is completely determined by the mean and standard deviation. (CDC 2005)

- 4) A symmetric distribution with one high point or mode, sometimes also called the bell curve. The average is one of many statistical calculations that, even for only a moderate amount of data, tend to have a distribution of that resemble the normal curve. (NIST/SEMATECH 2005b)
- 5) Normal distributions model (some) continuous random variables. Strictly, a Normal random variable should be capable of assuming any value on the real line, though this requirement is often waived in practice. For example, height at a given age for a given gender in a given racial group is adequately described by a Normal random variable even though heights must be positive. A continuous random variable X , taking all real values in the range $(-\infty, \infty)$ is said to follow a Normal distribution with parameters μ and σ if it has probability density function

$$f(x) = \frac{1}{\sigma\sqrt{2\pi}} \exp\left[-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2\right]$$

We write

$$X \sim N(\mu, \sigma^2)$$

This probability density function (pdf) is a symmetrical, bell-shaped curve, centered at its expected value μ . The variance is σ^2 . Many distributions arising in practice can be approximated by a Normal distribution. Other random variables may be transformed to normality. The simplest case of the normal distribution, known as the standard normal distribution, has expected value zero and variance one. This is written as $N(0,1)$.

(STEPS 1997)

RELATED TERMS: [probability density function](#), [Gaussian distribution](#), [Gaussian distribution model](#)

null hypothesis

- 1) The first step in testing for statistical significance in which it is assumed that the exposure is not related to disease. (CDC 2005)
- 2) In hypothesis testing, the hypothesis that an intervention has no effect, i.e., that there is no true difference in outcomes between a treatment group and a control group. Typically, if statistical tests indicate that the P value is at or above the specified α -level (e.g., 0.01 or 0.05), then any observed treatment effect is not statistically significant, and the null hypothesis cannot be rejected. If the P value is less than the specified α -level, then the treatment effect is statistically significant, and the null hypothesis is rejected. If a confidence interval (e.g., of 95% or 99%) includes zero treatment effect, then the null hypothesis cannot be rejected. (NLM/NICHHSR 2004)
- 3) The null hypothesis, H_0 , represents a theory that has been put forward, either because it is believed to be true or because it is to be used as a basis for argument, but has not been proved. For example, in a clinical trial of a new drug, the null hypothesis might be that the new drug is no better, on average, than the current drug. We would write H_0 : there is no difference between the two drugs on average. We give special consideration to the null hypothesis. This is due to the fact that the null hypothesis relates to the statement being tested, whereas the alternative hypothesis relates to the statement to be accepted if /

when the null is rejected. The final conclusion once the test has been carried out is always given in terms of the null hypothesis. We either “Reject H_0 in favor of H_1 ” or “Do not reject H_0 ”; we *never* conclude “Reject H_1 ,” or even “Accept H_1 .” If we conclude “Do not reject H_0 ,” this does not necessarily mean that the null hypothesis is true, it only suggests that there is not sufficient evidence against H_0 in favor of H_1 . Rejecting the null hypothesis then, suggests that the alternative hypothesis *may* be true. (STEPS 1997)

RELATED TERMS: [beta error](#), [type II error](#), [p-value](#)

one-hit model

- 1) A dose-response model based on a mechanistic argument that there is a response after a target site has been hit by a single biologically effective unit of dose within a given time period. The form of the model, a special case of the gamma, multistage, and Weibull models, is given by:

$$P(d) = 1 - e^{(-\lambda d)}$$

where:

$P(d)$ = probability of cancer from lifetime continuous exposure at dose rate d , and
 λ = fitted dose coefficient. (EPA 2003)

- 2) The basic dose-response model based on the concept that a tumor can be induced by a single receptor that has been exposed to a single quantum or effective dose unit of a chemical. (RAIS 2004, SRA 2004)
- 3) A mathematical model based on the biological theory that a single “hit” of some minimum critical amount of a carcinogen at a cellular target such as DNA can start an irreversible series events leading to a tumor. (EPA 2005b)

outlier

- 1) Observations whose value is so extreme that they appear not to be consistent with the rest of the dataset. In a process monitor, outliers indicate that assignable or special causes are present. The deletion of a particular outlier from a data analysis is easiest to justify when such an unusual cause has been identified. (NIST/SEMATECH 2005b)
- 2) An outlier is an observation in a data set that is far removed in value from the others in the data set. It is an unusually large or an unusually small value compared to the others. An outlier might be the result of an error in measurement, in which case it will distort the interpretation of the data, having undue influence on many summary statistics, for example, the mean. If an outlier is a genuine result, it is important because it might indicate an extreme of behavior of the process under study. For this reason, all outliers must be examined carefully before embarking on any formal analysis. Outliers should not routinely be removed without further justification. (STEPS 1997)

p-value

- 1) The probability value (p-value) of a statistical hypothesis test is the probability of getting a value of the test statistic as extreme as or more extreme than that observed by chance alone, if the null hypothesis H_0 , is true. It is the probability of wrongly rejecting the null

hypothesis if it is in fact true. It is equal to the significance level of the test for which we would only just reject the null hypothesis. The p-value is compared with the actual significance level of our test and, if it is smaller, the result is significant. That is, if the null hypothesis were to be rejected at the 5% significance level, this would be reported as “ $p < 0.05$.” Small p-values suggest that the null hypothesis is unlikely to be true. The smaller it is, the more convincing is the rejection of the null hypothesis. It indicates the strength of evidence for say, rejecting the null hypothesis H_0 , rather than simply concluding “Reject H_0 ” or “Do not reject H_0 .” (STEPS 1997)

- 2) In hypothesis testing, the probability that an observed difference between the intervention and control groups is due to chance alone if the null hypothesis is true. If P is less than the α -level (typically 0.01 or 0.05) chosen prior to the study, then the null hypothesis is rejected. (NLM/NICHSR 2004)
- 3) A probability calculated from a test statistic; it is the probability of obtaining data at least as extreme as has been obtained if the tested hypothesis were true. (NZ 2002)

RELATED TERMS: [null hypothesis](#)

parameter

- 1) A quantity used to calibrate or specify a model, such as parameters of a probability model (e.g., mean and standard deviation for a normal distribution). Parameter values are often selected by fitting a model to a calibration data set. (FAO/WHO 2003b)
- 2) A parameter is a value, usually unknown (and which therefore has to be estimated), used to represent a certain population characteristic. For example, the population mean is a parameter that is often used to indicate the average value of a quantity. Within a population, a parameter is a fixed value which does not vary. Each sample drawn from the population has its own value of any statistic that is used to estimate this parameter. For example, the mean of the data in a sample is used to give information about the overall mean in the population from which that sample was drawn. Parameters are often assigned Greek letters (e.g., σ), whereas statistics are assigned Roman letters (e.g., s). (STEPS 1997)

RELATED TERMS: [population](#)

Pareto distribution

The distribution with probability density function and distribution function:

$$P(x) = \frac{ab^a}{x^{a+1}} \quad (1)$$

$$D(x) = 1 - \left(\frac{b}{x}\right)^a \quad (2)$$

(Weisstein/MathWorld 2005a)

percentile

- 1) Any one of the points dividing a distribution of values into parts, each of which contains 1/100 of the values. For example, the 75th percentile is a value such that 75 percent of the values are less than or equal to it. (EPA 2004)
- 2) Percentiles values that divide the rank order of data into 100 equal parts. (NZ 2002)

point estimate

A single numerical value resulting from calculation(s). (AIHA 2000)

Poisson distribution

- 1) Poisson distributions model (some) discrete random variables (i.e., variables that may take on only a countable number of distinct values, such as 0, 1, 2, 3, 4,). Typically, a Poisson random variable is a count of the number of events that occur in a certain time interval or spatial area (statistics). (FAO/WHO 2003b, STEPS 1997)
- 2) The Poisson distribution is used to model the number of events occurring within a given time interval. The formula for the Poisson probability mass function is

$$p(x, \lambda) = \frac{e^{-\lambda} \lambda^x}{x!} \quad \text{for } x = 0, 1, 2, \dots$$

λ is the shape parameter which indicates the average number of events in the given time interval. (NIST/SEMATECH 2005a)

- 3) An important theoretical distribution used to model discrete events, especially the count of defects in an area. The Poisson distribution depends on one parameter, *lambda*, which represents the average defect density per observation area (or volume, time interval, etc.). The Poisson distribution assumes that the counts of defects in two non-overlapping observation units are independent. Further, the Poisson distribution assumes the distribution of defect counts depend only on the area in which they are to be observed. Unlike the binomial distribution, the Poisson distribution in principle sets no limit to the number of defects that can be observed in any area. Of particular interest the semiconductor industry, the Poisson probability of observing zero defects in a region of area A , $\exp\{-\lambda A\}$, is useful for yield modeling. (NIST/SEMATECH 2005b)

RELATED TERMS: [binomial distribution](#)

power

- 1) The probability of detecting a treatment effect of a given magnitude when a treatment effect of at least that magnitude truly exists. For a true treatment effect of a given magnitude, power is the probability of avoiding Type II error, and is generally defined as $(1 - \beta)$. (NLM/NICHSR 2004)
- 2) The power of a statistical hypothesis test measures the test's ability to reject the null hypothesis when it is actually false; that is, to make a correct decision. In other words, the power of a hypothesis test is the probability of not committing a type II error. It is calculated by subtracting the probability of a type II error from 1, usually expressed as:

$$\text{Power} = 1 - P(\text{type II error}) = (1 - \beta)$$

The maximum power a test can have is 1, the minimum is 0. Ideally we want a test to have high power, close to 1. (STEPS 1997)

RELATED TERMS: [beta error](#), [type II error](#)

probabilistic

A type of statistical modeling approach used to assess the expected frequency and magnitude of a parameter by running repetitive simulations using statistically selected inputs for the determinants of that parameter (e.g., rainfall, pollutants, flows, temperature). (EPA 2004)

probabilistic uncertainty analysis

Technique that assigns a probability density function to each input parameter, then randomly selects values from each of the distributions and inserts them into the exposure equation. Repeated calculations produce a distribution of predicted values, reflecting the combined impact of variability in each input to the calculation. Monte Carlo is a common type of probabilistic Uncertainty analysis. (EPA 1997a)

probability

- 1) Depending on philosophical perspective:
 - (a) The frequency with which we obtain samples within a specified range or for a specified category (e.g., the probability that an average individual with a particular mean dose will develop an illness).
 - (b) Degree of belief regarding the likelihood of a particular range or category. (FAO/WHO 2003b)
- 2) The subjective assignment of likelihood of future events; or the frequency of occurrence of an experimental or observations outcome. It refers to the uncertainty or partial knowledge associated with decision-making. (FDA 2002)
- 3) A basic concept that may be considered undefinable, expressing “degree of belief.” Alternatively, it is the limit of the relative frequency of an event in a sequence of n random trials as n approaches infinity: (Number of occurrences of the event) / n . (Last 1983)
- 4) The chance that a particular event will occur given the population of all possible events. (RAIS 2004)
- 5) A probability assignment is a numerical encoding of the relative state of knowledge. (SRA 2004)

probability density function**ACRONYM:** PDF

- 1) Probability density functions are particularly useful in describing the relative likelihood that a variable will have different particular values of x . The probability that a variable will have a value within a small interval around x can be approximated by multiplying $f(x)$ (i.e., the value of y at x in a PDF plot) by the width of the interval. (EPA 1998a)
- 2) The probability density function of a continuous random variable is a function that can be integrated to obtain the probability that the random variable takes a value in a given interval. (STEPS 1997)

RELATED TERMS: [sampling distribution](#)

probability distribution

- 1) A function that for each possible value of a discrete random variable takes on the probability of that value occurring, or a curve which specifies by means of the area under the curve over an interval the probability that a continuous random variable falls within the interval (the probability density function). (FAO/WHO 2003b)
- 2) Portrays the relative likelihood that a range of values is the true value of a treatment effect. This distribution often appears in the form of a bell-shaped curve. An estimate of

the most likely true value of the treatment effect is the value at the highest point of the distribution. The area under the curve between any two points along the range gives the probability that the true value of the treatment effect lies between those two points. Thus, a probability distribution can be used to determine an interval that has a designated probability (e.g., 95%) of including the true value of the treatment effect. (NLM/NICHSR 2004)

- 3) The probability distribution of a discrete random variable is a list of probabilities associated with each of its possible values. It is also sometimes called the probability function or the probability mass function. (STEPS 1997)

RELATED TERMS: [sampling distribution](#)

probable error

The magnitude of error which is estimated to have been made in determination of results. (RAIS 2004, SRA 2004)

probit analysis

A statistical transformation which will make the cumulative normal distribution linear. In analysis of dose-response, when the data on response rate as a function of dose are given as probits, the linear regression line of these data yields the best estimate of the dose-response curve. The probit unit is $y = 5 + Z(p)$, where p = the prevalence of response at each dose level and $Z(p)$ = the corresponding value of the standard cumulative normal distribution. (RAIS 2004, SRA 2004)

probit model

A dose-response model of the form:

$$P(d) = \gamma + (1 - \gamma) \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{\alpha + \beta d} e^{-\frac{u^2}{2}} du$$

where:

- $P(d)$ = the probability that an individual selected at random will respond at dose d , assuming a normal distribution of tolerances;
- α, β = fitted parameters; and
- γ = background response rate. (EPA 2003)

process criteria

The process control parameters (e.g., time, temperature, dose) at a specified step that can be applied to achieve a performance criteria. (CAC 2002)

quartiles

Median of the bottom half of data (lower quartile), or of the top half of the data (upper quartile). That is, values that divides the rank order of data into fourths. (NZ 2002)

random error

- 1) Unexplainable but characterizable variations in repeated measurements of a fixed true value resulting from processes that are random or statistically independent of each other, such as imperfections in measurement techniques. Some random errors could be reduced

by developing improved techniques. (FAO/WHO 2003b)

- 2) Indefiniteness of result due to finite precision of experiment. Measure of fluctuation in result upon repeated experimentation. (RAIS 2004, SRA 2004)

random sample

- 1) Sample selected from a statistical population such that each sample has an equal probability of being selected. (EPA 1997a)
- 2) A sample that is arrived at by selecting sample units such that each possible unit has a fixed and determinate probability of selection. (Last 1983)

random variable

A quantity which can take on any number of values but whose exact value cannot be known before a direct observation is made. For example, the outcome of the toss of a pair of dice is a random variable, as is the height or weight of a person selected at random from a city phone book. (EPA 2004)

range

- 1) The difference between the largest and smallest values in a measurement data set. (EPA 1997a)
- 2) In statistics, the difference between the largest and smallest values in a distribution. In common use, the span of values from smallest to largest. (CDC 2005)

rank correlation coefficient

A measure of the tendency for a Y value to increase, as it's associated X value increases. It allows for monotonic non-linear relationships. Measured by Spearman's coefficient (r_s), sometimes called "Spearman's rho" (ρ). (NZ 2002)

RELATED TERMS: [linear correlation coefficient](#)

ratio

- 1) The relation which one quantity or magnitude has to another of the same kind. It is expressed by the quotient of the division of the first by the second. (CancerWEB 2005)
- 2) The value obtained by dividing one quantity by another. (CDC 2005).

regression analysis

- 1) Procedures for finding the mathematical function which best describes the relationship between a dependent variable and one or more independent variables. In linear regression the relationship is constrained to be a straight line and least-squares analysis is used to determine the best fit. In logistic regression the dependent variable is qualitative rather than continuously variable and likelihood functions are used to find the best relationship. In multiple regression the dependent variable is considered to depend on more than a single independent variable. (CancerWEB 2005)
- 2) The analysis of the relationship between a dependent variable and one or more independent variables. Its purpose is to determine whether a relationship exists and the strength of the relationship. It is also used to determine the mathematical relationship between the variables, predict the values of the dependent variable and control other

independent variables when evaluating the effect of one or more independent variables. (ESOMAR 2001)

RELATED TERMS: [multiple regression](#)

sensitivity analysis

- 1) Process of changing one variable while leaving the others constant to determine its effect on the output. This procedure fixes each uncertain quantity at its credible lower and upper bounds (holding all others at their nominal values, such as medians) and computes the results of each combination of values. The results help to identify the variables that have the greatest effect on exposure estimates and help focus further information gathering efforts. (EPA 1997a)
- 2) A method used to examine the behavior of a model by measuring the variation in its outputs resulting from changes to its inputs. (CAC 1999, FAO/WHO 2003b)
- 3) A means to determine the robustness of a mathematical model or analysis (such as a cost-effectiveness analysis or decision analysis) that tests a plausible range of estimates of key independent variables (e.g., costs, outcomes, probabilities of events) to determine if such variations make meaningful changes the results of the analysis. Sensitivity analysis also can be performed for other types of study; e.g., clinical trials analysis (to see if inclusion/exclusion of certain data changes results) and meta-analysis (to see if inclusion/exclusion of certain studies changes results). (NLM/NICHSR 2004)

RELATED TERMS: *contrast with* [uncertainty analysis](#)

sigma g

ACRONYM: s g

Geometric standard deviation. (EPA 2003)

standard deviation

- 1) The most widely used measure of dispersion of a frequency distribution, equal to the positive square root of the variance. (CDC 2005)
- 2) A measure of spread or dispersion of a distribution. It estimates the square root of the average squared deviation from the distribution average, sometimes called the root-mean-square. Among all measures of dispersion, the standard deviation is the most efficient for normally distributed data. Also, unlike the range, it converges to a single value as more data from the distribution is gathered. (NIST/SEMATECH 2005b)
- 3) A measure of dispersion or variation, usually taken as the square root of the variance. (RAIS 2004, SRA 2004)
- 4) Standard deviation is a measure of the spread or dispersion of a set of data. It is calculated by taking the square root of the variance and is symbolised by s.d., or s. In other words

$$\sqrt{V(X)} = \sqrt{\sigma^2} = s$$

The more widely the values are spread out, the larger the standard deviation. (STEPS 1997)

RELATED TERMS: [distribution](#), [normal distribution](#)

standard error (of the mean)

- 1) A statistical index of the probability that a difference between two sample means is greater than zero. (CancerWEB 2005)
- 2) The standard deviation of a theoretical distribution of sample means about the true population mean. (CDC 2005)

standard geometric deviation

Measure of dispersion of values about a geometric mean; the portion of the frequency distribution that is one standard geometric deviation to either side of the geometric mean; accounts for 68% of the total samples. (RAIS 2004, SRA 2004)

standard normal deviation

Measure of dispersion of values about a mean value; the positive square root of the average of the squares of the individual deviations from the mean. (RAIS 2004, SRA 2004)

standardization

A set of techniques used to remove as far as possible the effects of differences in the age or other confounding variables when comparing two or more populations. (CancerWEB 2005)

statistic

- 1) A function of a random sample of data (e.g., mean, standard deviation, distribution parameters). (FAO/WHO 2003b)
- 2) A value calculated from sample data. (NIST/SEMATECH 2005b)
- 3) A statistic is a quantity that is calculated from a sample of data. It is used to give information about unknown values in the corresponding population. For example, the average of the data in a sample is used to give information about the overall average in the population from which that sample was drawn. It is possible to draw more than one sample from the same population and the value of a statistic will in general vary from sample to sample. For example, the average value in a sample is a statistic. The average values in more than one sample, drawn from the same population, will not necessarily be equal. Statistics are often assigned Roman letters (e.g., m and s), whereas the equivalent unknown values in the population (parameters) are assigned Greek letters (e.g., μ and σ). (STEPS 1997)

RELATED TERMS: [population](#), [sample](#), [sampling distribution](#)

statistical significance

- 1) An inference that the probability is low that the observed difference in quantities being measured could be due to variability in the data rather than an actual difference in the quantities themselves. The inference that an observed difference is statistically significant is typically based on a test to reject one hypothesis and accept another. (EPA 1992)
- 2) The probability that a result is not likely to be due to chance alone. By convention, a difference between two groups is usually considered statistically significant if chance could explain it only 5% of the time or less. Study design considerations may influence the a priori choice of a different level of statistical significance. (EPA 2003)
- 3) Conclusion that an intervention has a true effect, based upon observed differences in

outcomes between the treatment and control groups that are sufficiently large so that these differences are unlikely to have occurred due to chance, as determined by a statistical test. Statistical significance indicates the probability that the observed difference was due to chance if the null hypothesis is true; it does not provide information about the magnitude of a treatment effect. (NLM/NICHSR 2004)

- 4) The condition in which the p-value is smaller than an a priori value (the significance level, α). If $p < \alpha$ one can then say that a result is unlikely to have arisen merely by chance, and that the result is “statistically significant.” (NZ 2002)
- 5) The statistical significance determined by using appropriate standard techniques of statistical analysis with results interpreted at the stated confidence level and based on data relating species which are present in sufficient numbers at control areas to permit a valid statistical comparison with the areas being tested. (RAIS 2004, SRA 2004)

statistics

- 1) A branch of mathematics that deals with collecting, reviewing, summarizing, and interpreting data or information. Statistics are used to determine whether differences between study groups are meaningful. (ATSDR 2004)
- 2) The science and art of collecting, summarizing, and analyzing data that are subject to random variation. The term is also applied to the data themselves and to the summarization of the data. (CancerWEB 2005)

stochastic model

A mathematical model which takes into consideration the presence of some randomness in one or more of its parameters or variables. The predictions of the model therefore do not give a single point estimate but a probability distribution of possible estimates. Contrast with deterministic. We might distinguish demographic stochasticity that arises from the discreteness of individuals and individual events such as birth, and environmental stochasticity arising from more-or-less unpredictable interactions with the outside world. (Swinton 1999)

stochastic uncertainty

Also referred to as random error, q.v. (FAO/WHO 2003b)

stochastic variability

Sources of heterogeneity of values associated with members of a population that are a fundamental property of a natural system and that in practical terms cannot be modified, stratified or reduced by any intervention. For example, variation in human susceptibility to illness for a given dose for which there is no predictive capability to distinguish the response of a specific individual from that of another. Stochastic variability contributes to overall variability for measures of individual risk and for population risk. (FAO/WHO 2003b)

RELATED TERMS: [aleatory uncertainty](#)

subjective probability distribution

A probability distribution that represents an individual's or group's belief about the range and likelihood of values for a quantity, based upon that person's or group's expert judgment, q.v. (FAO/WHO 2003b)

t-distribution

The name given by Gosset (under his pseudonym “Student”) to a distribution that arises in the study of small samples, and in various other ways as well (Brooks 2001).

triangular distribution

- 1) The triangular distribution is a continuous distribution defined on the range $x \in [a, b]$ with probability density function

$$P(x) = \begin{cases} \frac{2(x-a)}{(b-a)(c-a)} & \text{for } a \leq x \leq c \\ \frac{2(b-x)}{(b-a)(b-c)} & \text{for } c < x \leq b \end{cases} \quad (1)$$

and distribution function

$$D(x) = \begin{cases} \frac{(x-a)^2}{(b-a)(c-a)} & \text{for } a \leq x \leq c \\ 1 - \frac{(b-x)^2}{(b-a)(b-c)} & \text{for } c < x \leq b, \end{cases} \quad (2)$$

(Weisstein/MathWorld 2005b)

- 2) A statistical distribution which requires the identification of *high*, *low*, and *most likely* values for each selected variable. The resultant data points form the basis for the triangular, or three-point distribution. (USDOT 1996)

type II error

SEE: [beta error](#)

uncertainty

- 1) Uncertainty represents a lack of knowledge about factors affecting exposure/toxicity assessments and risk characterization and can lead to inaccurate or biased estimates of risk and hazard. Some of the types of uncertainty include scenario uncertainty, parameter uncertainty, and model uncertainty. (EPA 1997a, EPA 2004)
- 2) Uncertainty occurs because of a lack of knowledge. It is not the same as variability. For example, a risk assessor may be very certain that different people drink different amounts of water but may be uncertain about how much variability there is in water intakes within the population. Uncertainty can often be reduced by collecting more and better data, whereas variability is an inherent property of the population being evaluated. Variability can be better characterized with more data but it cannot be reduced or eliminated. Efforts to clearly distinguish between variability and uncertainty are important for both risk assessment and risk characterization. (EPA 2003)
- 3) Lack of knowledge regarding the true value of a quantity, such as a specific characteristic (e.g., mean, variance) of a distribution for variability, or regarding the appropriate and adequate inference options to use to structure a model or scenario. These are also referred to as model uncertainty and scenario uncertainty. Lack of knowledge uncertainty can be reduced by obtaining more information through research and data collection, such as through research on mechanisms, larger sample sizes or more representative samples. (FAO/WHO 2003b)
- 4) An expression of the lack of knowledge, usually given as a range or group of plausible alternatives. (FDA 2002)

- 5) Ambiguity in microbial risk assessment arising from lack of knowledge about specific factors, parameters, or models. (ILSI 2000)
- 6) Imperfect knowledge concerning the present or future state of an organism, system or (sub) population under consideration. (IPCS/OECD 2004)
- 7) Imprecision and inaccuracy of an assessment or monitoring method. (KIWA 2004)
- 8) A term for the fuzzy concept of qualifying statement of what is known or concluded with quantitative statements of probability. Uncertainty usually has two aspects: (1) that created by the experimental (i.e., observational) error associated with taking observations, and (2) that implied by the use of imperfect models. (NIST/SEMATECH 2005b)

RELATED TERMS: [variability](#)

uncertainty analysis

- 1) A detailed examination of the systematic and random errors of a measurement or estimate (in this case a risk or hazard estimate); an analytical process to provide information regarding the uncertainty. (EPA 2004)
- 2) A method used to estimate the uncertainty associated with model inputs, assumptions, and structure/form. (CAC 1999)
- 3) A detailed examination of the systematic and random errors of a measurement or estimate; an analytical process to provide information regarding the uncertainty. (RAIS 2004, SRA 2004)

uncertainty factor

ACRONYM: ufs

- 1) One of several, generally 10-fold, default factors used in operationally deriving the RfD and RfC from experimental data. The factors are intended to account for (1) variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability); (2) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty); (3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and (5) uncertainty associated with extrapolation when the database is incomplete. (EPA 2003, EPA 2004)
- 2) Mathematical adjustments for reasons of safety when knowledge is incomplete. For example, factors used in the calculation of doses that are not harmful (adverse) to people. These factors are applied to the lowest-observed-adverse-effect-level (LOAEL) or the no-observed-adverse-effect-level (NOAEL) to derive a minimal risk level (MRL). Uncertainty factors are used to account for variations in people's sensitivity, for differences between animals and humans, and for differences between a LOAEL and a NOAEL. Scientists use uncertainty factors when they have some, but not all, the information from animal or human studies to decide whether an exposure will cause harm to people [also sometimes called a safety factor]. (ATSDR 2004)
- 3) Uncertainty Factor: Reductive factor by which an observed or estimated no-observed-adverse effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. (IPCS/OECD 2004)

- 4) One of several, generally 10-fold factors, used in operationally deriving the Reference Dose (RfD) from experimental data. UFs are intended to account for (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using LOAEL data rather than NOAEL data. (RAIS 2004)

RELATED TERMS: [assessment factor](#), [safety factor](#)

uniform distribution

- 1) The general formula for the probability density function of the uniform distribution is

$$f(x) = \frac{1}{B - A} \quad \text{for } A \leq x \leq B$$

where A is the location parameter and (B - A) is the scale parameter. The case where A = 0 and B = 1 is called the standard uniform distribution. The equation for the standard uniform distribution is

$$f(x) = 1 \quad \text{for } 0 \leq x \leq 1$$

The uniform distribution defines equal probability over a given range for a continuous distribution. For this reason, it is important as a reference distribution. (NIST/SEMATECH 2005a)

- 2) Uniform distributions model (some) continuous random variables and (some) discrete random variables. The values of a uniform random variable are uniformly distributed over an interval. For example, if buses arrive at a given bus stop every 15 minutes, and you arrive at the bus stop at a random time, the time you wait for the next bus to arrive could be described by a uniform distribution over the interval from 0 to 15. A discrete random variable X is said to follow a Uniform distribution with parameters a and b, written $X \sim \text{Un}(a,b)$, if it has probability distribution

$$P(X=x) = 1/(b-a) \quad \text{where } x = 1, 2, 3, \dots, n.$$

A discrete uniform distribution has equal probability at each of its n values. A continuous random variable X is said to follow a Uniform distribution with parameters a and b, written $X \sim \text{Un}(a,b)$, if its probability density function is constant within a finite interval [a,b], and zero outside this interval (with a less than or equal to b). The uniform distribution has expected value $E(X)=(a+b)/2$ and variance $\{(b-a)^2\}/12$. (STEPS 1997)

upper bound

A plausible upper limit to the true value of a quantity. This is usually not a true statistical confidence limit. (EPA 2003)

upper percentile

Values at the upper end of the distribution of values for a particular set of data. (EPA 1997a)

validation

- 1) Comparison of predictions of a model to independently estimated or observed values of the quantity or quantities being predicted, and quantification of biases in mean prediction

- and precision of predictions. (FAO/WHO 2003b)
- 2) A process by which a simulation model is evaluated for its accuracy in representing a system. (FDA 2002)
 - 3) Process by which the reliability and relevance of a particular approach, method, process, or assessment is established for a defined purpose. Different parties define “reliability” as establishing the reproducibility of the outcome of the approach, method, process, or assessment over time. “Relevance” is defined as establishing the meaningfulness and usefulness of the approach, method, process, or assessment for the defined purpose. (IPCS/OECD 2004)
 - 4) Obtaining evidence that the elements of the Water Safety Plan are effective. (KIWA 2004)

validity

- 1) The degree to which a measurement actually measures or detects what it is supposed to measure. (CDC 2005)
- 2) The extent to which a measure accurately reflects the concept that it is intended to measure. (NLM/NICHSR 2004)

variability

- 1) Variability arises from true heterogeneity across people, places, or time and can affect the precision of exposure estimates and the degree to which they can be generalized. The types of variability include: spatial, temporal, and inter-individual. (EPA 1997a)
- 2) Variability refers to true heterogeneity or diversity. For example, among a population that drinks water from the same source and with the same contaminant concentration, the risks from consuming the water may vary. This may be due to differences in exposure (i.e., different people drinking different amounts of water and having different body weights, different exposure frequencies, and different exposure durations) as well as differences in response (e.g., genetic differences in resistance to a chemical dose). Those inherent differences are referred to as variability. Differences among individuals in a population are referred to as inter-individual variability, differences for one individual over time is referred to as intra-individual variability. (EPA 2003)
- 3) Refers to the observed differences attributable to true heterogeneity or diversity in a population or exposure parameter. Examples include human physiological variation (e.g., natural variation in body weight, height, breathing rate, drinking water intake rate), weather variability, variation in soil types and differences in contaminant concentrations in the environment. Variability is usually not reducible by further measurement of study, but it can be better characterized. (EPA 2004)
- 4) Observed differences attributable to true heterogeneity or diversity in a population or exposure parameter. Variability implies real differences among members of that population. For example, different individuals have different intakes and susceptibility. Differences over time for a given individual are referred to as intra-individual variability. Differences over members of a population at a given time are referred to as inter-individual variability. Variability in microbial risk assessment cannot be reduced but only more precisely characterized. (FAO/WHO 2003b)
- 5) A description of differences among the individual members of a series or population.

(FDA 2002)

- 6) Observed differences attributable to true heterogeneity or diversity in a population or exposure parameter. Variability in microbial risk assessment cannot be reduced but only more precisely characterized. (ILSI 2000)
- 7) Intrinsic heterogeneity in a process or parameter. (KIWA 2004)

RELATED TERMS: [uncertainty](#)

variable

Any characteristic or attribute that can be measured. (CDC 2005)

variance

- 1) Law:

Government permission for a delay or exception in the application of a given law, ordinance, or regulation. (EPA 2005b)

Permission granted for a limited time (under stated conditions) for a person or company to operate outside the limits prescribed in a regulation. (CARB 2000)

- 2) Statistics:

A measure of the variation shown by a set of observations, defined by the sum of the squares of deviations from the mean, divided by the number of degrees of freedom in the set of observations. (Last 1983)

variation

The difference among individual outputs of a process. The causes of variation can be grouped into two major classes—common causes and special causes; the common cause variation can often be decomposed into variance components. (NIST/SEMATECH 2005b)

Differences between individuals within a population or among populations. (WHO 1999)

Weibull model

A dose-response model of the form:

$$P(d) = \gamma + (1 - \gamma)(1 - e^{-\beta d^\alpha})$$

where:

P(d) = the probability of a tumor (or other response) from lifetime, continuous exposure at dose d until age t (when tumor is fatal);

α = fitted dose parameter (sometimes called “Weibull” parameter);

β = fitted dose parameter;

γ = background response rate.

(EPA 2003)

zero order analysis

The simplest approach to quantification of a risk with a limited treatment of each risk component (e.g. source terms, transport, health effects, etc.). (RAIS 2004, SRA 2004)

5.10 RISK CHARACTERIZATION, RISK MANAGEMENT, AND POLICY TERMS

acceptable daily intake

ACRONYM: ADI

- 1) The amount of a chemical a person can be exposed to on a daily basis over an extended period of time (usually a lifetime) without suffering deleterious effects. (EPA 2003)
- 2) The ADI of a chemical is the estimate of the amount of a substance in food and/or drinking water, expressed on a bodyweight basis, that can be ingested daily over a lifetime without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. It is usually expressed in milligrams of the chemical per kilogram of body weight. (FAO/WHO 1997)
- 3) The estimated amount of a substance that can be consumed every day for a lifetime by humans without presenting a significant risk to their health, based on current scientific evidence. (FSA 2005)
- 4) Estimated maximum amount of an agent, expressed on a body mass basis, to which an individual in a (sub) population may be exposed daily over its lifetime without appreciable health risk. (IPCS/OECD 2004)
- 5) Estimate of the amount of a substance in food or drinking water, expressed on a body mass basis (e.g., mg or µg/kg body weight), which can be ingested daily over a lifetime by humans without appreciable health risk. (ILSI 2001)
- 6) An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. (RAIS 2004)

RELATED TERMS: [reference dose](#), [tolerable daily intake](#)

May also be known as “allowable daily intake.” Note, “allowable” does not imply that the level is “acceptable.”

acceptable risk

- 1) The likelihood of suffering disease or injury that will be tolerated by an individual, group, or society. The level of risk that is determined to be acceptable may depend on a variety of issues, including scientific data, social, economic, legal, and political factors, and on the perceived benefits arising from a chemical or process. (EPA 2004)
- 2) This is a risk management term. The acceptability of the risk depends on scientific data, social, economic, and political factors, and on the perceived benefits arising from exposure to an agent. (IPCS/OECD 2004)

actual risk

The damage to life, health, property, and/or the environment that may occur as a result of exposure to a given hazard. Risk assessment attempts to estimate the likelihood of actual risk. (EPA 2004)

added risk

The difference between the cancer incidence under the exposure condition and the background incidence in the absence of exposure. (RAIS 2004)

additional risk**ACRONYM:** AR

The calculated difference in risk of a particular condition between those who are exposed and those who are not. This measure is derived by subtracting the rate (usually incidence or mortality) of the disease among the unexposed persons (P_u) from the corresponding rate among the exposed (P_e), i.e., $AR = P_e - P_u$. The AR is an absolute measure of the excess risk attributed to exposure. (EPA 2003)

RELATED TERMS: [excess lifetime risk](#), [attributable risk](#), [risk difference](#)

aggregate risk

The risk resulting from aggregate exposure to a single agent or stressor. (EPA 2004)

appropriate level of protection**ACRONYM:** ALOP

Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal, or plant life or health within its territory. (CAC 2002)

attributable risk

The rate of a disease in exposed individuals that can be attributed to the exposure. This measure is derived by subtracting the rate (usually incidence or mortality) of the disease among non-exposed persons from the corresponding rate among exposed individuals. (RAIS 2004, SRA 2004)

RELATED TERMS: [additional risk](#), [odds ratio](#)

cancer risk

A theoretical risk for getting cancer if exposed to a substance every day for 70 years (a lifetime exposure). The true risk might be lower. (ATSDR 2004)

comparison value**ACRONYM:** CV

Calculated concentration of a substance in air, water, food, or soil that is unlikely to cause harmful (adverse) health effects in exposed people. The CV is used as a screening level during the public health assessment process. Substances found in amounts greater than their CVs might be selected for further evaluation in the public health assessment process. (ATSDR 2004)

confounder

- 1) A condition or variable that is both a risk factor for disease and associated with an exposure of interest. This association between the exposure of interest and the confounder (a true risk factor for disease) may make it falsely appear that the exposure of interest is associated with disease. (EPA 2003)
- 2) A variable that introduces bias into an association between a causal factor and an effect. (A bias resulting from an unbalanced distribution of other causal factors, or markers for such factors, among people in different exposure categories.) (NZ 2002)
- 3) Variables that may introduce differences between cases and controls which do not reflect

differences in the variables of primary interest. (RAIS 2004, SRA 2004)

RELATED TERMS: [matching](#)

confounding factor

SEE: [confounder](#)

control point

ACRONYM: CP

A step in the water supply at which contamination is prevented reduced or eliminated or minimized and which, if collectively in compliance, would ensure that water quality targets are met. CPs are points in the water supply where it is possible to set operational and/or critical limits, monitor those limits and take corrective action in response to a detected deviation before the water becomes unsafe. Often these points are control measures that are specifically designed to control a hazard. (KIWA 2004)

Control points are part of Hazard Analysis Critical Control Points (HACCP) and are used in a broader context than just water, for example HACCP was originally created for food and beverage production.

control processes

Control processes are measures that are in place or new options under evaluation that are part of the risk mitigation strategy. Examples of control processes are wastewater treatment plants and pasteurization. Alternative control processes may be evaluated using risk assessment. (ILSI 2000 text)

criteria

Descriptive factors taken into account by EPA in setting standards for pollutants. For example, water quality criteria describe the concentration of pollutants that most fish can be exposed to for an hour without showing acute effects. (EPA 2005e)

critical limits

A criterion which measures performance of the control point to ensure that the control point will deliver water of a quality consistent that meets the water quality targets. Exceeding the Critical Limit implies that the Control point is no longer in compliance with the Water Safety Plan and there is an increased risk of water quality failing to meet the Health Target. (KIWA 2004)

decontamination

- 1) Removal of harmful substances such as noxious chemicals, harmful bacteria or other organisms, or radioactive material from exposed individuals, rooms and furnishings in buildings, or the exterior environment. (EPA 2005b, RAIS 2004)
- 2) The reduction or removal of a chemical, biological, or radiological material from the surface of a structure, area, object, or person. (MERREA 2005)

disinfection

- 1) disinfectant - A chemical that destroys vegetative forms of harmful microorganisms, but does not ordinarily kill bacterial spores. (EPA 2005e)

- 2) Killing of infectious agents outside the body by direct exposure to chemical or physical agents. (MERREA 2005)
- 3) The process designed to kill most microorganisms in water, including essentially all pathogens. (CRCWQT 2002)

excess death

The excess over statistically expected deaths in a population within a given time interval. Attempts are made to relate excess deaths to specific causes. Note that since every person can (and must) die only once, there can be no excess deaths over all time. (SRA 2004)

excess lifetime risk

The additional or extra risk of developing cancer due to exposure to a toxic substance incurred over the lifetime of an individual. (EPA 2003)

expected deaths

The number of deaths statistically expected in a population in a given time interval obtained by summing the product of age-, sex-, and race-specific mortality rates from a standard population and person-years in each age, sex, and race category in the study population. (RAIS 2004, SRA 2004)

expected loss

The quantity obtained by multiplying the magnitude of health or environmental effect loss by the probability (or risk) of that loss and adding the products. The expected loss is the average loss over a large number of trials; one must reflect on the appropriateness of its use in cases for which there will be only one, or a few, trials. (RAIS 2004, SRA 2004)

guidance value

Value, such as concentration in air or water, which is derived after allocation of the reference dose among the different possible media (routes) of exposure. The aim of the guidance value is to provide quantitative information from risk assessment to the risk managers to enable them to make decisions. (IPCS/OECD 2004)

RELATED TERMS: [reference dose](#)

individual risk

- 1) The probability that an individual will experience an adverse effect. (EPA 2003)
- 2) The risk or hazard to an individual in a population rather than to the population as a whole. (EPA 2004)
- 3) The risk to an individual rather than to a population. (MERREA 2005, RAIS 2004, SRA 2004)

level of concern**ACRONYM:** LOC

The concentration in air of an extremely hazardous substance above which there may be serious immediate health effects to anyone exposed to it for short periods. (EPA 2005b)

Phrases that have specific definitions in one context may also have common vernacular

meanings. For example, “level of concern” could easily have a general meaning that encompasses a variety of possible “levels.” However, LOC is a specific jargon term used for air toxics that has not been adopted for water contaminants or pathogens.

management goal

A goal is a general statement of the desired outcome for the overall decision that would solve the problem or take maximum advantage of the opportunity, etc., for example, “Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated wetlands, freshwater rivers, and ponds.” (EPA 1998a)

management objective

An objective is a more specific statement of the desired outcome. It should be specific enough to allow scientists to develop measures from them for a risk assessment. Objectives for Waquoit Bay included: “Restore and maintain self-sustaining native fish populations and their habitat.” Objectives include an entity (native fish in this case), some attribute (population), and a desired state or direction of change (self-sustainability). Note that assessments endpoints are similar in that they include an entity and an attribute, but do not include a desired state or direction of change. (EPA 1998a)

margin of safety

- 1) Maximum amount of exposure producing no measurable effect in animals (or studied humans) divided by the actual amount of human exposure in a population. (EPA 2005b)
- 2) For some experts the Margin of Safety has the same meaning as the Margin of Exposure, while for others, the Margin of Safety means the margin between the reference dose and the actual exposure dose or concentration. (IPCS/OECD 2004)

RELATED TERMS: [margin of exposure](#)

microbiological criteria

A microbiological criteria for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area, or lot. (CAC 2002)

mitigation

Measures taken to reduce adverse impacts on the environment. (EPA 2005b)

multipathway risk

The risk resulting from exposure to pollutants through more than one pathway. (EPA 2004)

RELATED TERMS: [multipathway exposure](#), [multipathway assessment](#)

peer review

- 1) The process by which manuscripts submitted to health, biomedical, and other scientifically oriented journals and other publications are evaluated by experts in appropriate fields (usually anonymous to the authors) to determine if the manuscripts are of adequate quality for publication. (NLM/NICHSR 2004)

- 2) A process whereby scientific and technical research and analysis is subject to outside review and comments by individuals or a panel qualified to review and comment upon the material. Many scientific and technical journals conduct peer reviews before studies are published. Governmental agencies involved in scientific and technical missions and programs also often use peer reviews to guide research agendas, evaluate research proposals and studies, and evaluate proposed health-based environment standards. (NYS 1998)

performance criteria

The required microbiological outcome of one or more control measures at a step or combination of steps that contribute to assuring the safety of a food. (CAC 2002)

performance standard

The requirement for certain results or outcomes. Usually used to describe results-based regulations, performance standards shy away from prescribing practices or specifications, and do not stipulate the type of technology or other requirements to be used when complying with the regulations. (NYS 1998)

permissible dose

The dose of a chemical that may be received by an individual without the expectation of a significantly harmful result. (EPA 2005b)

permissible exposure limit

ACRONYM: PEL

- 1) An occupational health standard to safeguard employees against dangerous chemicals or contaminants in the workplace. (Last 1983)
- 2) The legal limit for occupational exposure to airborne concentrations of several hundred agents. Established by OSHA (U.S. Occupational Safety and Health Administration (REAP 1995)

population attributable risk

SEE: [attributable risk](#)

potential risk

Estimated likelihood, or probability, of injury, disease, or death resulting from exposure to a potential environmental hazard. (EPA 2004)

public health approach

Regulatory and voluntary focus on effective and feasible risk management actions at the national and community level to reduce human exposures and risks, with priority given to reducing exposures with the biggest impacts in terms of the number affected and severity of effect. (EPA 2005b)

public health context

The incidence, prevalence, and severity of diseases in communities or populations and the

factors that account for them, including infections, exposure to pollutants, and other exposures or activities. (EPA 2005b)

qualitative uncertainty estimate

A detailed examination, using qualitative information, of the systematic and random errors of a measurement or estimate. (EPA 2004)

quality assurance

- 1) An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (EPA 2004)
- 2) Quality Assurance/Quality Control: A system of procedures, checks, audits, and corrective actions to ensure that all EPA research design and performance, environmental monitoring and sampling, and other technical and reporting activities are of the highest achievable quality. (EPA 2005b, RAIS 2004)

RELATED TERMS: [quality control](#)

quality assurance project plan

A document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. (EPA 2004)

quality control

The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of its users. The aim is to provide data quality that is satisfactory, adequate, and dependable. (EPA 2004)

RELATED TERMS: [quality assurance](#)

relative risk

ACRONYM: RR

- 1) The relative measure of the difference in risk between the exposed and unexposed populations in a cohort study. The relative risk is defined as the rate of disease among the exposed divided by the rate of the disease among the unexposed. A relative risk of 2 means that the exposed group has twice the disease risk as the unexposed group. (EPA 2003)
- 2) A comparison of the risk of some health-related event such as disease or death in two groups. (CDC 2005)
- 3) The ratio of two incidence rates (strictly, rate ratio for person-time data); or the ratio of two cumulative incidences (strictly, risk ratio for count data). For “rare” diseases these ratios are approximately equal (hence, in common usage, both are referred to as relative risk). Loosely used to mean odds ratio in case-control studies since, for “rare” diseases, they may approximate one another. (NZ 2002)
- 4) The ratio of the rate of the disease (usually incidence or mortality) among those exposed to the rate among those not exposed. (RAIS 2004, SRA 2004)

RELATED TERMS: [risk ratio](#)

relative risk assessment

Estimating the risks associated with different stressors or management actions. (EPA 2005b)

risk-based decision-making

An approach to regulatory decision-making in which such decisions are made solely based on the results of a probabilistic risk analysis. (USNRC 2005)

risk-based targeting

The direction of resources to those areas that have been identified as having the highest potential or actual adverse effect on human health and/or the environment. (EPA 2005b)

risk management policy

Guidance provided for value judgment or policy choices, and provision for apportionment of adequate resources and peer review. (CAC 2002)

risk monitoring

Process of following up the decisions and actions within risk management in order to ascertain that risk containment or reduction with respect to a particular hazard is assured. Risk monitoring is an element of risk management. (IPCS/OECD 2004)

risk profile

- 1) A description of a food safety problem and its context so as to guide further risk management action. (CAC 2002)
- 2) The description of the food safety problem and its context. (CAC 2003)
- 3) An overall summary of the context in which a risk is being analyzed, including: a description of the risk(s) considered, values threatened by the risk, social perception of the risk, who benefits from producing the risk, who benefits from managing the risk, and characteristics of the risk, the risk-producer and the risk-bearer, which are pertinent to successful management of the risk. (OMAF 1997)
- 4) A description of the food safety problem and its context. Risk profiling is the process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to various risk management decisions. The risk profile would include identifying aspects of hazards relevant to prioritizing and setting the risk assessment policy and aspects of the risk relevant to the choice of safety standards and management options. (USDA 2004)

risk ratio

SEE: [relative risk](#)

risk reduction

Actions that can decrease the likelihood that individuals, groups, or communities will experience disease or other health conditions. (ATSDR 2004)

subjective judgment

SEE: [expert judgment](#)

tolerable daily intake

Analogous to acceptable daily intake. The term “tolerable” is used for agents that are not deliberately added such as contaminants in food. (IPCS/OECD 2004)

tolerable intake

Estimated maximum amount of an agent, expressed on a body mass basis, to which each individual in a (sub) population may be exposed over a specified period without appreciable risk. (IPCS/OECD 2004)

unit risk

- 1) The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 g/L in water, or 1 g/m³ in air. The interpretation of unit risk would be as follows: if unit risk = 1.5×10^{-6} g/L, 1.5 excess tumors are expected to develop per 1,000,000 people if exposed daily for a lifetime to 1 g of the chemical in 1 liter of drinking water. (EPA 2003)
- 2) The unit risk factors (URFs) provide estimates of the risks due to a unit inventory of contaminant (i.e., risk/gram or risk/curie). URFs can be calculated for water, soil, air, and radiation. URFs can be used to calculate risk for quantities greater than unity only if the relationship is linear. (RAIS 2004)

unit risk estimate**ACRONYM:** URE

The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 μg/L in water, or 1 μg/m³ in air. The interpretation of unit risk would be as follows: if the water unit risk = 2×10^{-6} μg/L, 2 excess tumors may develop per 1,000,000 people if exposed daily for a lifetime to 1 μg of the chemical in 1 liter of drinking water. (EPA 2004)

water quality target

The maximum levels of microbiological hazards in drinking water, which are considered acceptable for human consumption, preferably in a quantitative and verifiable manner as described by official state authorities. (KIWA 2004)

water safety plan**ACRONYM:** WSP

A management plan developed to address all aspects of water supply that are under the direct control of the water supplier focused on the control of water production, treatment and distribution to deliver drinking water. (KIWA 2004)

weight-of-evidence**ACRONYM:** WOE

In determining carcinogenicity, a system for characterizing the extent to which the available data support the hypothesis that an agent causes an adverse health effect in humans. For example,

under EPA's 1986 cancer risk assessment guidelines, the WOE was described by categories "A through E," Group A for known human carcinogens through Group E for agents with evidence of noncarcinogenicity. The approach outlined in EPA's proposed guidelines for carcinogen risk assessment (1996 and updates) considers all scientific information in determining whether and under what conditions an agent may cause cancer in humans, and provides a narrative approach to characterize carcinogenicity rather than categories. (EPA 2003, 2004)

5.11 ECONOMIC TERMS

benefit

The degree to which effects are judged desirable. (SRA 2004)

benefit-cost analysis

An economic method for assessing the benefits and costs of achieving alternative health-based standards at given levels of health protection. (EPA 2005b)

RELATED TERMS: [cost-benefit analysis](#)

contingent valuation method

The use of surveys of individuals to elicit their preferences, measured in monetary terms (willingness to pay, or WTP), for a specified improvement in their health outcomes. It circumvents the absence of markets for health outcomes by presenting survey respondents with hypothetical markets in which they are asked their WTP for the improvement in question. (USDA 2004)

cost-benefit analysis

- 1) An evaluation of the costs which would be incurred versus the overall benefits of a proposed action, such as the establishment of an acceptable exposure level of a pollutant. (EPA 2004)
- 2) A quantitative evaluation of the costs which would have incurred by implementing an environmental regulation versus the overall benefits to society of the proposed action. (EPA 2005b)
- 3) A comparison of alternative interventions in which costs and outcomes are quantified in common monetary units. (NLM/NICHSR 2004)
- 4) A formal quantitative procedure comparing costs and benefits of a proposed project or act under a set of pre-established rules. To determine a rank ordering of projects to maximize rate of return when available funds are unlimited, the quotient of benefits divided by costs is the appropriate form; to maximize absolute return given limited resources, benefits-costs is the appropriate form. (RAIS 2004, SRA 2004)

RELATED TERMS: [benefit-cost analysis](#)

cost-effectiveness analysis

- 1) A comparison of alternative interventions in which costs are measured in monetary units and outcomes are measured in non-monetary units, e.g., reduced mortality or morbidity. (NLM/NICHSR 2004)
- 2) An approach for comparing alternative programs or regulations when the benefits are difficult or impossible to translate into dollar terms. The benefits are referred to as 'effectiveness measures.' Costs are measured in monetary terms. Cost-effectiveness analysis employs a ratio analysis approach, for ranking alternative programs or regulations. (NYS 1998)

cost-of-illness analysis

A determination of the economic impact of a disease or health condition, including treatment

costs; this form of study does not address benefits/outcomes. (NLM/NICHSR 2004)

cost-of-illness method**ACRONYM:** COI

An approach that is used to estimate the societal costs of a particular illness or injury in a given time frame (typically a one-year period). The approach typically focuses on two main types of societal costs associated with the particular illness or injury: direct medical and non-medical costs and indirect costs of lost productivity due to morbidity or premature mortality. (USDA 2004)

direct costs

Costs associated with resources expended for health care (compare with indirect costs); does not include lost wages. (USDA 2004)

RELATED TERMS: [indirect costs](#)

direct medical costs

The costs of resources for medical treatment (such as the cost of a physician visit). (USDA 2004)

direct non-medical costs

Costs incurred in connection with a health intervention or illness, but which are not expended for medical care itself (such as the transportation costs associated with a physician visit). (USDA 2004)

disability-adjusted life year**ACRONYM:** DALY

- 1) A unit of health care status that adjusts age-specific life expectancy by the loss of health and years of life due to disability from disease or injury. DALYs are often used to measure the global burden of disease. (NLM/NICHSR 2004)
- 2) A quantitative indicator of burden of disease that reflects the total amount of healthy life lost, to all causes, whether from premature mortality or from some degree of disability during a period of time. (World Bank 2000)

RELATED TERMS: *contrast with* [quality-adjusted life year](#)

discount rate

- 1) The interest rate used to discount or calculate future costs and benefits so as to arrive at their present values, e.g., 3% or 5%. This is also known as the opportunity cost of capital investment. Discount rates are usually based on government bonds or market interest rates for cost of capital whose maturity is about same as the time period during which the intervention or program being evaluated. For example, the discount rate used by the US federal government is based on the Treasury Department cost of borrowing funds and will vary, depending on the period of analysis. (NLM/NICHSR 2004)
- 2) A rate used in determining a present value equivalent of a future stream of dollars. The lower the discount rate, the higher the present value of a future stream of dollars. (USDA 2004)

discounting

- 1) The process used in cost analyses to reduce mathematically future costs and/or benefits/outcomes to their present value. These adjustments reflect that given levels of costs and benefits occurring in the future usually have less value in the present than the same levels of costs and benefits realized in the present. (NLM/NICHSR 2004)
- 2) A process by which benefits or costs realized in future periods are converted to their present value. Discounting adjusts for the time value of money (i. e., a dollar one possesses now is worth more than a dollar that one will receive in two years, since it could have been invested and earned interest in the intervening period). Discounting also incorporates assumptions about future inflation effects. (NYS 1998)
- 3) A method for adjusting the value of future costs and benefits to an equivalent value today to account for time preference and opportunity cost, that is, a dollar today is worth more than a dollar a year from now (even if inflation is not considered). (USDA 2004)

disutility costs

Costs include all the factors leading to the diminished well-being of a patient due to illness or premature death. Disutility costs of illness typically measure the amount of money (or another measure of well-being) the average patient would be willing to give up to avoid an illness or premature death (such as lower wages received for low-risk jobs). Disutility may include a wide range of costs, including those for pain and suffering, inconvenience, time lost from regular activities, and productivity losses. (USDA 2004)

healthy-years equivalents**ACRONYM:** HYE

The number of years of perfect health that are considered equivalent to (i.e., have the same utility as) the remaining years of life in their respective health states. (NLM/NICHSR 2004)

hedonic wage studies

Statistical analyses that estimate the effect of intrinsic job characteristics, such as health risks, fringe benefits, or autonomy, on pay. (USDA 2004)

human capital approach

A method for estimating the impact of an individual's illness or premature death on society by measuring the discounted value of his/her productivity loss (labor earnings) due to morbidity or premature mortality. (USDA 2004)

incidence-based costs

The total lifetime costs of new cases of a disease or injury that occur during a certain period of time. (USDA 2004)

incremental cost (analysis)

The extra or additional costs imposed as a result of a regulatory policy. The term incremental is interchangeable with "marginal." If compliance requirements have different levels or degrees of achieving certain targets, then incremental costs can be associated with each level of compliance

from the current state. (NYS 1998)

indirect costs

The resources forgone either to participate in an intervention or as the result of a health condition (such as earnings forgone because of loss of time from work). (USDA 2004)

RELATED TERMS: [direct costs](#)

marginal costs

The incremental cost of increasing output of a good or service by a small amount. (EPA 2003b)

opportunity costs

The monetary value of the resources used in providing a specific set of health-care services, valued in terms of forgone alternative uses. (USDA 2004)

productivity loss

The monetary value of output that would have been produced in the absence of an illness, disability, injury, morbidity, or premature mortality. (USDA 2004)

RELATED TERMS: [direct costs](#), [indirect costs](#)

quality-adjusted life year

ACRONYM: QALY

A unit of health care outcomes that adjusts gains (or losses) in years of life subsequent to a health care intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost-utility across different interventions and health problems. Analogous units include disability-adjusted life years (DALYs) and healthy-years equivalents (HYEs). (NLM/NICHSR 2004).

RELATED TERMS: [quality of life](#); *contrast with* [disability-adjusted life year](#)

quality of life

- 1) Refers to the level of comfort, enjoyment, ability to pursue daily activities. Often used in discussions of treatment options. (CancerWEB 2005)
- 2) A health effects factor in the EPA/ILSI Framework. Life expectancy, chronic debilitation, or episodic bouts of disease can all be considered in quality of life. (ILSI 2000 text)

RELATED TERMS: [quality-adjusted life year](#)

willingness to pay

ACRONYM: WTP

A measure of the value an individual would place on reducing risk of death or illness. It is the maximum dollar amount the individual would be willing to give up in a given hypothetical risk-reducing situation. (USDA 2004)

5.12 CHEMICAL RISK ASSESSMENT TERMS

baseline condition

A phase conducted during an experiment where the independent variable, an event or variable manipulated by a researcher, is absent. A baseline is used for comparison when the independent variable is subsequently introduced. (RRTC-PBS 2003)

bioassay

- 1) An assay for determining the potency (or concentration) of a substance that causes a biological change in experimental animals. (EPA 2003)
- 2) A test conducted in living organisms (in vivo) or with living cells (in vitro) to determine the hazard or potency of a chemical by its effect on animals, isolated tissues, or microorganisms. (OAQPS 1989)
- 3) A test to determine the relative strength of a substance by comparing its effect on a test organism with that of a standard preparation. (EPA 2005b)
- 4) A method of testing a material's effects on living organisms. (EPA 2005e)
- 5) Using living organisms to measure the effect of a substance, factor, or condition. (SRA 2004)

bioavailability

- 1) The degree to which a substance becomes available to the target tissue after administration or exposure. (EPA 2003)
- 2) The ability to be absorbed and available to interact with the metabolic processes of an organism. (EPA 2004)
- 3) A measure of the degree to which a dose of a substance becomes physiologically available to the body tissues depending upon adsorption, distribution, metabolism, and excretion rates. (OAQPS 1989)
- 4) The rate and extent to which an agent can be absorbed by an organism and is available for metabolism or interaction with biologically significant receptors. Bioavailability involves both release from a medium (if present) and absorption by an organism. (IPCS 2004)

biological half-life

The time required for a biological system (such as a human or animal) to eliminate, by natural processes, half the amount of a substance (such as a radioactive material) that has been absorbed into that system. (RAIS 2004, SRA 2004)

chronic toxicity

- 1) The capacity of a substance to cause adverse human health effects as a result of chronic exposure. (EPA 2003)
- 2) The effects of long term or repeated low level exposures to a toxic substance (cancer, liver damage, reproductive disorders, etc.). (EPA 2005e)

frank effect level**ACRONYM:** FEL

- 1) A level of exposure or dose which produces irreversible, adverse effects at a statistically or biologically significant increase in frequency or severity between those exposed and those not exposed. (EPA 2003)
- 2) Exposure level which produces unmistakable adverse effects, such as irreversible functional impairment or mortality, at a statistically or biologically significant increase in frequency or severity between an exposed population and its appropriate control. (RAIS 2004)

half-life**ACRONYM:** $t_{1/2}$

- 1) The time it takes for half the original amount of a substance to disappear. In the environment, the half-life is the time it takes for half the original amount of a substance to disappear when it is changed to another chemical by bacteria, fungi, sunlight, or other chemical processes. In the human body, the half-life is the time it takes for half the original amount of the substance to disappear, either by being changed to another substance or by leaving the body. In the case of radioactive material, the half life is the amount of time necessary for one half the initial number of radioactive atoms to change or transform into another atom (that is normally not radioactive). After two half lives, 25% of the original number of radioactive atoms remain. (ATSDR 2004)
- 2) (a) The time required for a pollutant to lose one-half of its original concentration. For example, the biochemical half-life of DDT in the environment is 15 years. (b) The time required for half of the atoms of a radioactive element to undergo self-transmutation or decay (half-life of radium is 1620 years). (c) The time required for the elimination of half a total dose from the body. (EPA 2005b)

hazard index**ACRONYM:** HI

- 1) The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-term duration exposures. (EPA 2004)
- 2) Potential noncarcinogenic (systemic) effects are characterized by comparing projected intakes of chemicals to toxicity values (i.e., reference doses). The numerical risk or hazard quotient estimate that results is a ratio. The ratio of the intake over the reference dose (hazard index) is compared to unity (1.0). If the quotient is less than 1, then the systemic effects are assumed not to be of concern; if the hazard quotient is greater than 1, then the systemic effects are assumed to be of concern. The hazard index is the sum of hazard quotients. (RAIS 2004)

hazard quotient**ACRONYM:** HQ

- 1) The ratio of a single substance exposure level over a specified time period (e.g., chronic) to a reference value (e.g., an RfC) for that substance derived from a similar exposure period. (EPA 2004)

- 2) The ratio of estimated site-specific exposure to a single chemical from a site over a specified period to the estimated daily exposure level, at which no adverse health effects are likely to occur. (EPA 2005b)

hazard ratio

A term used to compare an animal's daily dietary intake of a pesticide to its LD 50 value. A ratio greater than 1.0 indicates that the animal is likely to consume a dose amount which would kill 50 percent of animals of the same species. (EPA 2005b)

human equivalent concentration

ACRONYM: HEC

- 1) The human concentration (for inhalation exposure) of an agent that is believed to induce the same magnitude of toxic effect as the experimental animal species concentration or dose. This adjustment may incorporate toxicokinetic information on the particular agent, if available, or use a default procedure, such as assuming that daily oral doses experienced for a lifetime are proportional to body weight raised to the 0.75 power. (EPA 2003)
- 2) Exposure concentration for humans that has been adjusted for dosimetric differences between experimental animal species and humans to be equivalent to the exposure concentration associated with observed effects in the experimental animal species. If occupational human exposures are used for extrapolation, the human equivalent concentration represents the equivalent human exposure concentration adjusted to a continuous basis. (RAIS 2004)

RELATED TERMS: [human equivalent dose](#)

human equivalent dose

ACRONYM: HED

A dose which, when administered to humans, produces an effect equal to that produced by a dose in animals. (EPA 2005b, RAIS 2004)

RELATED TERMS: [human equivalent concentration](#)

interspecies dose conversion

The process of extrapolating from animal doses to human equivalent doses. (EPA 2003)

key event

A "key event" is an empirically observable precursor step that is itself a necessary element of the mode of action or is a biologically based marker for such an element. (EPA 2005a)

lethal concentration-50

ACRONYM: LC₅₀

- 1) Median level concentration, a standard measure of toxicity. It tells how much of a substance is needed to kill half of a group of experimental organisms in a given time. (EPA 2005b)
- 2) A concentration of a pollutant or effluent at which 50% of the test organisms die; a common measure of acute toxicity. (EPA 2005e)

RELATED TERMS: [lethal dose](#), [lethal dose-50](#)

linearized multistage procedure

A modification of the multistage model, used for estimating carcinogenic risk, that incorporates a linear upper bound on extra risk for exposures below the experimental range. (EPA 2003)

RELATED TERMS: [multistage model](#)

lower limit on effective dose-10

ACRONYM: LED₁₀

The 95% lower confidence limit of the dose of a chemical needed to produce an adverse effect in 10 percent of those exposed to the chemical, relative to control. (EPA 2003)

lowest observed adverse effect level

ACRONYM: LOAEL

- 1) The lowest level of a stressor evaluated in a test that causes statistically significant differences from the controls. (EPA 1998a)
- 2) The lowest exposure level at which there are biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group. (EPA 2003)
- 3) The lowest exposure level in a study or group of studies at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group. Also referred to as lowest-effect level (LEL). (EPA 2004)
- 4) The lowest level of a stressor that causes statistically and biologically significant differences in test samples as compared to other samples subjected to no stressor. (EPA 2005b)
- 5) The lowest dose in a toxicity study resulting in adverse health effects. (EPA 2005e)
- 6) The lowest tested dose of a substance that has been reported to cause harmful (adverse) health effects in people or animals. (ATSDR 2004)

lowest-observed effect level

ACRONYM: LOEL or LEL

In a study, the lowest dose or exposure level at which a statistically or biologically significant effect is observed in the exposed population compared with an appropriate unexposed control group. (EPA 2003)

non-cancer risk

The potential or probability to incur a noncancer health effect (e.g., lead poisoning, neurological disorders, liver disease) due to exposure to hazardous substances. (TAFBERP 2005)

non-threshold toxicant

A chemical for which there is no exposure level below which an adverse health outcome is not expected to occur. Such substances are considered to pose some risk of harm at any level of exposure. (EPA 2004)

no-observed-adverse-effect level**ACRONYM:** NOAEL

- 1) The highest exposure level at which there are no biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse or precursors of adverse effects. (EPA 2003)
- 2) An highest exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse, nor precursors to adverse effects. (EPA 2004)
- 3) An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered as adverse, or as precursors to adverse effects. In an experiment with several NOAELs, the regulatory focus is primarily on the highest one, leading to the common usage of the term NOAEL as the highest exposure without adverse effects. (EPA 2005b)
- 4) The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals. (ATSDR 2004)

no-observed-effect level**ACRONYM:** NOEL

- 1) The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls. (EPA 1998a)
- 2) An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any effect between the exposed population and its appropriate control. (EPA 2003, EPA 2005b)

pharmacokinetic model

A model that can be used to predict the time course of absorption, distribution, metabolism, and excretion of a foreign substance in an organism's body (e.g., pesticide). (EPA 1998b)

pharmacokinetics

- 1) The study of the time course of absorption, distribution, metabolism, and excretion of a foreign substance (e.g., a drug or pollutant) in an organism's body. (EPA 1992)
- 2) The field of study concerned with defining, through measurement or modeling, the absorption, distribution, metabolism, and excretion of drugs or chemicals in a biological system as a function of time. (EPA 1995b)
- 3) The study of the way that drugs move through the body after they are swallowed or injected. (EPA 2005b)

physiologically based pharmacokinetic model**ACRONYM:** PBPK model

- 1) A model that estimates the dose to a target tissue or organ by taking into account the rate of absorption into the body, distribution among target organs and tissues, metabolism, and excretion. (EPA 2003)

- 2) A computer model that describes what happens to a chemical in the body. This model describes how the chemical gets into the body, where it goes in the body, how it is changed by the body, and how it leaves the body. (ATSDR 2004)

reference concentration**ACRONYM:** RfC

An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (EPA 2003)

reference dose**ACRONYM:** RfD

- 1) An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (EPA 2003)
- 2) The RfD is a numerical estimate of a daily oral exposure to the human population, including sensitive subgroups such as children, that is not likely to cause harmful effects during a lifetime. RfDs are generally used for health effects that are thought to have a threshold or low dose limit for producing effects. (EPA 2005b)
- 3) An EPA estimate, with uncertainty or safety factors built in, of the daily lifetime dose of a substance that is unlikely to cause harm in humans. (ATSDR 2004)
- 4) An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. (IPCS/OECD 2004)

RELATED TERMS: [acceptable daily intake](#)

reference value**ACRONYM:** RfV

An estimation of an exposure for [a given duration] to the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse effects over a lifetime. It is derived from a BMDL, a NOAEL, a LOAEL, or another suitable point of departure, with uncertainty/variability factors applied to reflect limitations of the data used. (EPA 2003)

slope factor

An upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100. (EPA 2003)

subchronic study

A toxicity study designed to measure effects from subchronic exposure to a chemical. (EPA 2003)

synergism

An interaction of two or more chemicals that results in an effect greater than the sum of their separate effects. (EPA 2005b)

synergistic effect

- 1) A biologic response to multiple substances where one substance worsens the effect of another substance. The combined effect of the substances acting together is greater than the sum of the effects of the substances acting by themselves. (ATSDR 2004)
- 2) Joint effects of two or more agents, such as drugs that increase each other's effectiveness when taken together. (RAIS 2004, SRA 2004)

RELATED TERMS: [additive effect](#), [antagonistic effect](#)

threshold toxicant

A chemical for which there is an exposure level below which an adverse health outcome is not expected to occur. (EPA 2004)

toxic substance

A chemical, physical, or biological agent that may cause an adverse effect or effects to biological systems. (EPA 2003)

toxicant

- 1) A harmful substance or agent that may injure an exposed organism. (EPA 2005b)
- 2) A substance that kills or injures an organism through chemical or physical action or by altering the organism's environment; for example, cyanides, phenols, pesticides, or heavy metals; especially used for insect control. (RAIS 2004, SRA 2004)

RELATED TERMS: [toxin](#)

toxicity

- 1) Deleterious or adverse biological effects elicited by a chemical, physical, or biological agent. (EPA 2003)
- 2) The degree to which a substance or mixture of substances can harm humans or environmental receptors. (EPA 2004, EPA 2005b)
- 3) The quality or degree of being poisonous or harmful to plant, animal, or human life. (CRCWQT 2002)
- 4) Inherent property of an agent to cause an adverse biological effect. (IPCS/OECD 2004)
- 5) The degree of danger posed by a substance to animal or plant life. (RAIS 2004, SRA 2004)

toxicity assessment

Characterization of the toxicological properties and effects of a chemical, with special emphasis

on establishment of dose-response characteristics. (EPA 2004, EPA 2005b)

toxicity test

Biological testing (usually with an cell system, invertebrate, fish, or small mammal) to determine the adverse effects of a compound. (EPA 2004)

toxicodynamics

The determination and quantification of the sequence of events at the cellular and molecular levels leading to a toxic response to an environmental agent (sometimes referred to as pharmacodynamics). (EPA 2003)

toxicokinetics

- 1) The determination and quantification of the time course of absorption, distribution, biotransformation, and excretion of chemicals (sometimes referred to as pharmacokinetics). (EPA 2003)
- 2) The terms “toxicokinetics” and “pharmacokinetics” describe the same processes; “pharmacokinetics” was derived in reference to drugs or other substances used for treatment, while “toxicokinetics” has more recently been used to refer to nonpharmaceutical toxic substances such as environmental pollutants. (IPCS 2001)

toxicology

- 1) The study of harmful interactions between chemical, physical, or biological agents and biological systems. (EPA 2003)
- 2) The study of harmful interactions between chemicals and biological systems. (EPA 2004)
- 3) Study of poisons, their effects, antidotes and detection. (CRCWQT 2002)

5.13 ECOLOGICAL RISK ASSESSMENT TERMS

critical effect

The first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases. (EPA 2003, EPA 2005b)

ecological risk

In the context of risk assessment, the expected frequency or probability of undesirable (or “unacceptable adverse”) ecological effects resulting from exposure to known or expected stressors. (Navy 2003)

ecological risk assessment

- 1) The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. (EPA 2004)
- 2) The application of a formal framework, analytical process, or model to estimate the effects of human action(s) on a natural resource and to interpret the significance of those effects in light of the uncertainties identified in each component of the assessment process. Such analysis includes initial hazard identification, exposure and dose response assessments, and risk characterization. (EPA 2005b, RAIS 2004)

effective concentration

ACRONYM: EC₅₀

A concentration expected to cause an effect in 50% of a group of test organisms. (EPA 1998a)

effective dose

ACRONYM: ED₁₀

The dose corresponding to a 10% increase in an adverse effect, relative to the control response. (EPA 2003)

exposure frequency

- 1) The number of occurrences in a given time frame (e.g., a lifetime) of contact or co-occurrence of a stressor with a receptor. (EPA 2004)
- 2) The number of exposure events in an exposure duration. (IPCS 2004)

exposure indicator

A characteristic of the environment measured to provide evidence of the occurrence or magnitude of a response indicator's exposure to a chemical or biological stress. (EPA 2005b, RAIS 2004)

indicator organisms

A species, whose presence or absence may be characteristic of environmental conditions in a particular area of habitat; however, species composition and relative abundance of individual components of the population or community are usually considered to be a more reliable index of water quality. (SRA 2004)

RELATED TERMS: [indicator](#), [exposure-response](#)

measure of ecosystem and receptor characteristics

Measures that influence the behavior and location of organisms of interest, stressor distribution, and organismal life-history characteristics that may affect exposure or response to the stressor. (EPA 1998a)

measure of effect

- 1) Describes change assessment endpoint (or surrogate) attributes in response to a stressor to which it is exposed. Dose-response data are an example. (EPA 1998a)
- 2) A measurable characteristic of ecological entity that can be related to an assessment endpoint; e.g. a laboratory test for eight species meeting certain requirements may serve as a measure of effect for an assessment endpoint, such as survival of fish, aquatic, invertebrate, or algal species under acute exposure. (EPA 2005b)

measurement endpoint

- 1) A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. Also known as “measure of effect.” (EPA 2004)
- 2) A measurable characteristic of ecological entity that can be related to an assessment endpoint; e.g. a laboratory test for eight species meeting certain requirements may serve as a measure of effect for an assessment endpoint, such as survival of fish, aquatic, invertebrate or algal species under acute exposure. (EPA 2005b)
- 3) Measurable (ecological) characteristic that is related to the valued characteristic chosen as an assessment point. (IPCS/OECD 2004)

RELATED TERMS: [measure of effect](#)

microenvironment method

- 1) A method used in predictive exposure assessments to estimate exposures by sequentially assessing exposure for a series of areas (microenvironments) that can be approximated by constant or well-characterized concentrations of a chemical or other agent. (EPA 1992)
- 2) A method for sequentially assessing exposure for a series of microenvironments that can be approximated by constant concentrations of a stressor. (EPA 2005b)

primary effect

An effect where the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect; compare with definition for secondary effect). (EPA 1998, 2005b)

prospective risk assessment

An evaluation of the future risks of a stressor not yet released into the environment or of future conditions resulting from an existing stressor. (EPA 1998a)

receptor

- 1) Ecology:
 - (a) The ecological entity exposed to the stressor. (EPA 1998, EPA 2005b)
 - (b) In fate/transport modeling, the location where impacts are predicted. (EPA 2004)

- (c) In a non-modeling context, the entity which is exposed to an environmental stressor. (EPA 2004)
- 2) Molecular biology:
 - (a) A molecule on the surface of a cell that serves as a recognition or binding site for antigens, antibodies or other cellular or immunologic components. (NIAID 2000)

receptor population

- 1) The exposed individual relative to the exposure pathway considered. (EPA 1999B)
- 2) People who could come into contact with hazardous substances. (ATSDR 2004)

RELATED TERMS: [exposure pathway](#)

retrospective risk assessment

An evaluation of the causal linkages between observed ecological effects and a stressor in the environment. (EPA 1998a)

secondary effect

An effect where the stressor acts on one component of the ecosystem, which in turn has an effect on the component of interest (synonymous with indirect effects). (EPA 1998a)

RELATED TERMS: *contrast with* [primary effect](#)

stressor

- 1) Any physical, chemical, or biological entity that can induce an adverse response. (EPA 1998a)
- 2) Physical, chemical, or biological entities that can induce adverse effects on ecosystems or human health. (EPA 2005b)
- 3) The term “stressor” includes the connotation that the adverse response can be the result of a lack of something – such as a habitat – which would also be called a “stressor.” The term “agent” does not have this connotation, and is only used to denote a causative entity that actually physically exists as part of the environment. (IPCS 2001)
- 4) Any entity, stimulus, or condition that can modulate normal functions of the organism or induce an adverse response (e.g., agent, lack of food, drought). (IPCS 2004)

stressor-response profile

A summary of data on the effects of a stressor and the relationship of the data to the assessment endpoint. (EPA 1998a)

5.14 EPA TERMS

biosolid

- 7) Nutrient-rich organic materials resulting from the treatment of domestic sewage in a treatment facility. When treated and processed, these residuals can be recycled and applied as fertilizer to improve and maintain productive soils and stimulate plant growth. Biosolids are treated sewage sludge. Biosolids are carefully treated and monitored and must be used in accordance with regulatory requirements. (EPA 2006)
- 8) The organic product that results from sewage treatment processes (otherwise referred to as sewage sludge) (NSWEPA 2004)
- 9) Biosolids products: organics containing any component of biosolids, including pure biosolids in the form of liquid or cake, or derived organics such as compost, lime sludges or pellets (NSWEPA 2004)

RELATED TERMS: [sludge](#)

cancer slope factor

ACRONYM: CSF

An upper bound (approximating a 95% confidence limit) on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship; that is, for exposures corresponding to risks less than 1 in 100. This term is usually used to refer to oral slope factors (i.e., slope factors used for assessing ingestion exposure). (EPA 2004)

critical concentration

An ambient chemical concentration expressed in units of g/m^3 and used in the operational derivation of the inhalation RfC. This concentration will be the NOAEL Human Equivalent Concentration (HEC) adjusted from principal study data. (EPA 2003)

critical study

The study that contributes most significantly to the qualitative and quantitative assessment of risk. Also called Principal Study. (EPA 2003)

effluent

- 1) Waste material being discharged into the environment, either treated or untreated. Effluent generally is used to describe water discharges to the environment, although it can refer to stack emissions or other material flowing into the environment. (EPA 1992)
- 2) Wastewater—treated or untreated—that flows out of a treatment plant, sewer, or industrial outfall. Generally refers to wastes discharged into surface waters. (EPA 2005b)
- 3) Wastewater discharged from a point source, such as a pipe. (EPA 2005e)
- 4) Treated or untreated liquid waste material that is discharged into the environment from a point source, such as a wastewater treatment plant or an industrial facility. (NCSU 1997)
- 5) Waste material discharged into the environment, treated or untreated. Generally refers to water pollution. (SRA 2004)

health assessment

An evaluation of available data on existing or potential risks to human health posed by a Superfund site. The Agency for Toxic Substances and Disease Registry (ATSDR) of the Department of Health and Human Services (DHHS) is required to perform such an assessment at every site on the National Priorities List. (EPA 2005b)

health consultation

In a public health assessment, a review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical. (EPA 2004)

limited evidence

A term used in evaluating study data for the classification of a carcinogen by the 1986 U.S. EPA guidelines for carcinogen risk assessment. This classification indicates that a causal interpretation is credible but that alternative explanations such as chance, bias, and confounding variables could not be completely excluded. (EPA 2003)

lines of evidence

Information derived from different sources or by different techniques that can be used to describe and interpret risk estimates. Unlike the term “weight of evidence,” it does not necessarily assign quantitative weights to information. (EPA 1998a)

maximum individual risk**ACRONYM:** MIR

An MIR represents the highest estimated risk to an exposed individual in areas that people are believed to occupy. (EPA 2004)

RELATED TERMS: [worst case](#)

nonpoint source

- 1) A diffuse pollution source (i.e., without a single point of origin or not introduced into a receiving stream from a specific outlet). The pollutants are generally carried off the land by storm water. Common non-point sources are agriculture, forestry, urban, mining, construction, dams, channels, land disposal, saltwater intrusion, and city streets. (EPA 2005b)
- 2) A contributing factor to water pollution that cannot be traced to a specific spot; like agricultural fertilizer runoff, sediment from construction. (SRA 2004)

pollution

Any substances in water, soil, or air that degrade the natural quality of the environment, offend the senses of sight, taste, or smell, or cause a health hazard. The usefulness of the natural resource is usually impaired by the presence of pollutants and contaminants. (EPA 2005e)

residual risk

The extent of health risk from air pollutants remaining after application of the Maximum Achievable Control Technology (MACT). (EPA 2004)

sludge

- 1) A semi-solid residue from any of a number of air or water treatment processes; can be a hazardous waste. (EPA 2005b)

RELATED TERMS: [biosolid](#)

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